

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Samuel Cavallaro et al.
Serial No. : 09/991,200
Filed : November 16, 2001
For : Fully Intergrated Critical Care Workstation
Examiner : Lilian Vo
Art Unit : 2127

Rule 131 Declaration of Joseph Elaz

I, Joseph Elaz, declare as follows.

1. I am an inventor named in the above identified subject patent application.

2. I am informed and believe that claims 1-7 of the subject patent application are rejected with reference to U.S. Patent No. 6,793,625-Cavallaro et al.

3. Attached hereto and made part of this declaration are the following Exhibits:

i. Exhibit A is a electronic mail message from Sam Cavallaro dated July 28, 2000 which discloses the details of the invention which are disclosed in Exhibit B.

ii. Exhibit B is a true copy of a signed Requirement Specification Release Version; VFU Document # 1-5957282 dated April 18, 2000 which discloses the invention claimed in the subject application.

4. I conceived, with my co-inventors, the invention disclosed in the subject application in the United States and reduced the invention to practice on or before November 13, 2000 as evidenced by Exhibits A and B.

5. The invention as claimed in claim 1 comprises a critical care workstation. The work Station includes a display device and a processor, coupled to the display device. The processor executes a general purpose operating system, controlling execution of a selected non-real-time application program for displaying images representing non-real-time data on the display device and a real-time kernel, controlling execution of a process for displaying images representing real-time data on the display device simultaneously with the display of the non-real-time data. Circuitry, responsive to user input, selects the non-real-time display program from among a plurality of available non-real-time display programs. Claims 2-7 are dependent on claim 1 and include additional features of the invention.

The features of the above claimed invention are outlined and disclosed in the highlighted sections of Exhibit A in combination with page 7 in section 4.1 entitled "Requirements Introduction" of Exhibit B. Specifically, the workstation having a display and processor coupled thereto is derived from section 4.1 on page 7 of Exhibit B as well as section 6.4 entitled "Display" on pages 19 – 20 of Exhibit B. The operating system controlling execution of a non-real time application process is derived from Exhibit A in combination with section 6.3 entitled "Software" on page 19 of Exhibit B in further combination with section 6.7 entitled "Patient View" on pages 21 – 23 of Exhibit B. The kernel for controlling the simultaneous display of real-time data with non-real-time data is derived from Exhibit A in combination with section 6.7.14.1 as well as in section 6.7.16 and 6.7.17 on pages 24 – 25 of Exhibit B. The circuitry, responsive to user input, that selects the non-real-time display program from among a plurality of available non-real time display programs is derived from Exhibit A as well as from section 5.11 entitled "Hardware" on pages 11 – 14 of Exhibit B in combination with Section 6.7 of Exhibit B as discussed above.

6. All statements made herein to my knowledge are true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful statements may jeopardize the validity of the Application or any patent issued thereon.

29 MARCH 05

Date

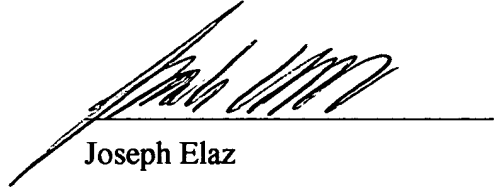

Joseph Elaz

Exhibit A

Cavallaro Sam

From: Cavallaro Sam
Sent: Friday, July 28, 2000 4:20 PM
To: 'lawrence.edelman@sc.siemens.com'
Cc: Buresh Bill; Scholz Wolfgang (EMG-PCS); Elaz Yossi; Kelly Cliff; Ortlam Dieter [PCS]; Cavallaro Sam
Subject: FW: Patents on the Zeus Project

Dear Larry(Please ignore the first message) ,

We have several ideas for patents on the Zeus Project. What additional info do you need?

1. SW Patent: Deterministic display, control and robustness of real-time physiological waveforms simultaneously with non real-time time applications.

People Involved: Dieter Ortlam, Sam Cavallaro

Arguments

- Solution solves robustness and realtime requirements at the same time - *non-real time does not interfere w/ real time*
- Within a 3 tier layer software architecture a vertical separation for the realtime process was designed: data propagation directly from network layer to graphics card
The separation of executables provides robustness, the direct connection of network and graphics ensures the realtime requirement.
- Complete separation of executables: driving of the display is separated, no coupled embedding (like OLE)
- Although the separation of the executables, the RT Application is visually embedded in the Host Application
- In case that the non realtime application is blocked, the realtime application is reachable by a keyboard accellerator (eg. Ctrl-R) or reachable by mouse on a 1pix strip at the right edge of the screen. This will work even when the non-realtime app covers the realtime app completly.
- Simultaneous running of all applications, both real-time and non real-time on the same display with a single mouse click.
- Simultaneously viewing of Real-time application on a single screen with multiple windows some of which are non real-time
- Control real-time waveform configuration while viewing or running non real-time applications
- Standard Hardware and Operating system built from standard PC technology and configured for real-time determinism

2. Zeus S/W uses standard NT4.0 Operating System to display Monitoring waveforms and parameters, Ventilation loops and parameters, Medical Imaging, Hospital Information Systems, Remote Bedside Viewing, ECG, Charting and Internet Pages within the Patient Vicinity Area.

People: Yossi Elaz, Wolfgang Scholz, Dieter Ortlam, Sam Cavallaro

Arguments

- Previous patient monitoring products have displayed real-time waveforms using real-time kernels
Imaging products do not have hard real-time requirements.
- Hospital Information Systems do not have hard real-time requirements

Some companies have one or two

video switching - between monitor & PC - but no direct data

Higher resolution

ECG - system DICOM

Margarette Solar 9800 HP

expandable - open system

open clinical system

- Charting does not have hard real-time requirements
- Composition of applications is unique
- Standard PC applications such as Internet Explorer are available with Medical Applications and Real-time Medical Applications
- All applications are embedded with a single user interface
- Common look and feel for control and view of all Applications, Service and Installation
- Synchronization of Patient access for all applications
- Multiple sources of Information, Real-time network and non-real-time Hospital Network

3. Zeus H/W designed with standard PC hardware but certain added capabilities make it a fully patient vicinity display device

People: Cliff Kelly, Sam Cavallaro, Yossi Elaz

Argument: See attached



Siemens Med WS.doc

4. Zeus User Interface allows fast single mouse clicks to view user saved views of clinical information from different applications that are running simultaneously.

Transferred via PCMCIA card.
People: Bill Buresh, Dieter Ortlan, Wolfgang Scholz
Arguments: TBD

pop-up setup.
CUSTOM VIEW - integration w/ other

medical applications
and individual saved views.

5. Configurable Home Screen

OP TO 9
+
←

6. SMART VIEWS

- Patient
- Imaging
- CIS (chart)
- Hospital Info
- Remote view
- ECG

simultaneously

MEDICAL APPS
Trends

Loops

Waveforms

ST (segment of ECG wave)

parameters

12 lead ECG

mini trends

OCRG (moving trends)

Event recall

Calc (drug)

Lab data

Alarm History

up to 31 waveforms
on one display.

Exhibit B

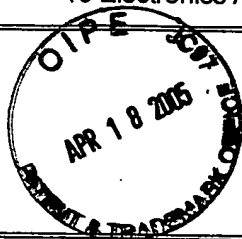
Siemens Medical Systems, Inc.
Electromedical Group

16 Electronics Avenue • Danvers, MA 01923

PREFIX
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PART NUMBER
59 57 282

REV
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REQUIREMENT SPECIFICATION

REQ SPEC ZEUS

SHEET 1 OF

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TYPE NUMBER
E553U

REVISIONS

REV	ECO	DESCRIPTION	CHK	DWN	ENG	DATE
0	13654	RELEASE TO DESIGN SPECIFICATIONS	PLO	ALG	SC	01/19/00
1	13875	REVISED & UPDATED	KLM	ALG	SC/WB	05/01/00

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ENGINEER

S. CAVALLERO

DATE

01/19/00

QUALITY ASSURANCE

C. HERTEL

DATE

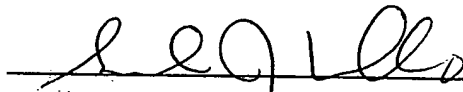
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ZEUS

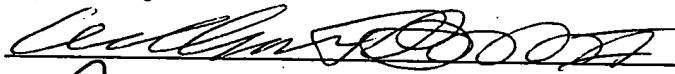
Requirement Specification
Release Version: VF0
Document # 1-5957282
Rev1

Approval Signature:

Date

 4/18/00

Project Manager: Sam Cavallaro

 4/18/00


Clinical Engineering: Bill Buresh

 4/28/00

Marketing: Mark Kolnsberg

 4/27/00

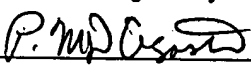

Quality Assurance/Regulatory: Connie Hertel

 4/27/00

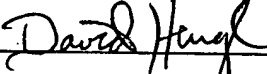
Service and Support: John Ginty

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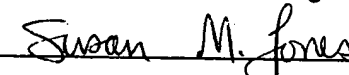
Manufacturing: Tracy Smith

 4/27/00  4/27/00

Electrical Engineering: Cliff Kelly/Pete D'Agostino

 4-27-00

Product Validation: Dave Hengl

 4/18/00

Software Engineering: Susan Jones

Mechanical: Mike Lysik

 4/27/00

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Purpose

1. Scope

This document contains the requirements for the Zeus VF0 PC and Integrated display system. The Zeus receives Physiological Parameters from the Apollo monitoring line compatible with the VF0 release. This product does not serve as a front end to those parameters. The requirements for specific physiological parameters can be found in the Apollo Series and Hercules Requirement Specification documents.

2. References

The following documents contain product requirements from earlier releases.

Apollo Series Requirement Specification: Document # 1-5204487 VC0 Rev 2

Apollo Series Requirement Specification: Document # 1-5739722 VC2 Rev 0

Apollo Series Requirement Specification: Document # 1-5945352 VC3 Rev 0

Apollo Series Requirement Specification: Document # 1-5736959 VE0 Rev 2

Apollo Product Hazard Description: Document # 1-5739730

Hercules Requirements Specification: Document # 1-5206144 VC0 Rev 0

Hercules Requirements Specification: Document # 1-5737460 VC1 Rev 0

SC 7000/9000XL Software Installation Instructions: Document # T902-02-7600

3. Definitions

Zeus Shell: The Zeus shell replaces the standard windows user interface display. From the Zeus Shell the user can access and control applications and displays.

Work Flow: The work flow defines the major user tasks associated with accessing a patient. The Zeus work flow presents an order of tasks but allows the user to navigate freely.

Clinical UNIT: A Clinical UNIT such as "ICU" sets the stage for the overall look and feel of the device. It is our intent that clinicians in each clinical environment should feel that this device was designed specifically for them.

The first release of the Zeus shall be geared toward the ICU. Future releases shall include default setups for other clinical environments.

Clinical Rounds Display: A Clinical Rounds Display is a compilation of relevant clinical data/information to best allow a clinician to evaluate the status of a patient on a single display. For example, an Cardiology Clinical Rounds display could be comprised of a Real Time extended monitor view, 12 lead display, ST parameter values and Trends. In the first release the user shall be able to customize there own clinical rounds display.

Auto Smart View (future): An Auto Smart View is the recall of a particular Clinical Round View based on a particular trigger. In the first release the triggers shall be predefined.

For example, based on an arrhythmia event trigger a Hemodynamic display, trends, event recall, and arrhythmia setup menu could be displayed .

Note: Smart view triggers shall be based on existing alarms within the Apollo series, no new alarms shall be required as triggers.

Patient Setup: Patient setup allows the user signal control and alarm setup of the Apollo parameters.

Clinical Procedures: (FUTURE, not implemented in this release)

Clinical Procedures allow the user to access clinically relevant applications from a single trigger on a single display such as Wedge, and C.O. and Hemodynamic calculations.

Alarm Monitor Window: a window that contains a similar parameter and waveform view to the associated Apollo display. The Alarm Monitor window mirrors the Apollo visual alarm annunciation.

Extended Windows: a series of windows that allows the user to extend their monitoring display capability, including; waveforms, parameters, trends, blood gas values, and calculation results.

Parameters on the Extended windows do not annunciate alarms (visual/audio).

Task Card: metaphor for the user interface task hierarchy, similar to a folder tab that presents relevant information and controls on display.

Monitor Video: When NT is not available during startup and NT Failure, the Zeus display will switch to a mirrored view of the Apollo monitor (straight VGA).

Zeus Video: Standard Zeus display running on Windows NT.

Apollo Monitor: References the Apollo Monitor throughout the specification include the SC 7000, SC 8000, and SC 900XL, unless indicated otherwise.

4. Revision History

Revision	Date	Updated by:	Description of Changes
Draft	18-Oct-99	Bill Buresh	Initial draft
Draft2	21-Dec-99	Bill Buresh	Second draft, updates from review
Rev0	28-Dec-99	Bill Buresh	Final markups
Rev1 Draft	8-Mar-2000	Bill Buresh	Resolved TBDs, updates from design reviews, reformat of table of contents based on the new process template
Rev1 Draft2	5-Apr-2000	Bill Buresh	Draft for follow up review
Rev1	12-Apr-2000	Bill Buresh	Updates from final review

4.1. Requirements Introduction

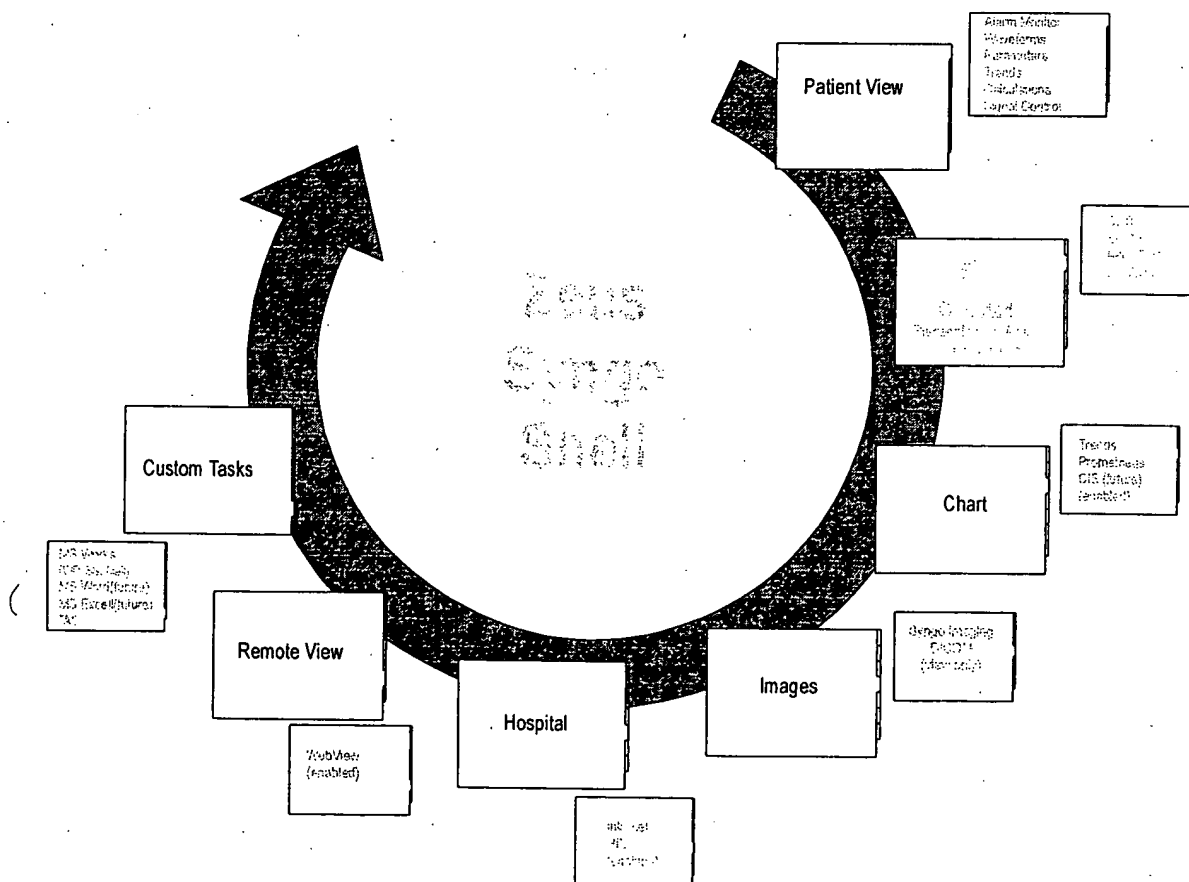
Zeus consists of a specialized medical grade PC and a software program that allows the user to **extend** the viewing capability of the Apollo monitor and **integrate** additional patient information on a single display with the intention of improving clinician work efficiency.

Real Time Physiological monitoring is provided locally from a connected bedside monitor. While additional patient information can reside remotely on a clinical information system, HIS, Web, Lab Department, Imaging Department, etc.

The intended users in the first release are; Intensivist, Cardiologist, ICU Nurse, Anesthesiologist, Respiratory Therapist, Radiologist, Bio Medical Technician and Service Personnel.

The user shall be able to display 1280x1024 resolution (**Future 1600x1200**). With this added display real estate, the user shall be able to display more parameters on the Zeus than currently possible with the Apollo monitor alone and run applications such as Prometheus, WebView, Syngo Imaging, and Microsoft Works etc. Below is an overview of the Zeus Shell contents and structure.

Figure 1: Zeus Shell – Work Flow Overview



As can be seen in the workflow, the intention is to provide the user to access and integrate patient information throughout the hospital at the bedside.

The Software Architecture is based on Syngo, providing Zeus with a common look and feel across the Siemens Medical divisions. The metaphor for the graphical user interface is a task card resembling a folder tab.

Below is a brief description of each of the available task cards.

Patient View: default main screen display of the Zeus user interface that allows the user to display an alarm monitor and extended monitoring windows. The patient view task card has a restricted application set so as to eliminate unpredictable windowing behavior (i.e. eliminate the covering of patient data and hidden window displays).

The Patient View shall be able to take on the "personality" of a given Clinical Unit and accommodate the "triggers" that motivate an individual clinician to approach the monitor such as: Clinician's Rounds, Alarm Situations, Patient Setup (signal control) and Clinical Procedures (**future-not implemented in this release**).

ECG (future- not implemented in this release): allows the user to access ECG data from CRS, MUSE, and MegaCart system.

Chart: allows the user to access Trends, Prometheus (future access to CIS).

Images: allows the user to access the Syngo Imaging program (DICOM).

Hospital: allows the user to the HIS and an Intranet Brower.

Remote View: allows the user access to WebView (view patients both in and out of the care unit)

Custom Tasks: allows the user to access word processing, mail, and spreadsheet programs, while also allowing the user to combine applications from other task cards. This special task card is needed in the cases where some programs windows are not predictable in their windowing behavior.

The Alarm Monitor displays visual alarm annunciation for alarming parameters on the Apollo display. Parameters in Extended windows do not alarm.

Zeus is intended to serve as a secondary monitoring display in this release. A video switch is provided to allow for automatic switching to the monitor VGA display when Windows NT fails. The user can access the standard Windows NT desktop from within the Zeus Shell.

This functionality shall be provided by development of a PC board (Zeus PC) that shall be integrated with the following Siemens product lines:

- Pick and Go Monitoring
- SC 6000 SC 7000, SC 8000, SC 9000XL, SC 9000

The operating system on the Zeus PC is Windows NT 4.0 Service Pack 5 or greater with the capability to also use Embedded NT release 4.0. The NT platform allows continuous expansion of clinical application windows (developed by Siemens PCS) or existing NT medical applications (integrated into the Zeus environment by Siemens PCS).

A UPS shall be incorporated to provide a power backup so as to allow the device to operate for up to 2 minutes of during a blackout in a 24-hour period before powering down safely. It is intended that the Zeus be connected to the Hospital Emergency Backup system to provide for any additional operating backup.

The Zeus shall be designed to be able to run off a single power supply pigtailed to an IDS. However, in this case, an additional power supply is required if a "local recorder" is connected directly to a monitor. A recorder connector cover shall be available to block the connection of a local recorder in this case. It is suggested that networked recorders are used with Zeus, thus avoiding the necessity of an additional power supply.

The KION group in Solna have expressed interest in using the Zeus as a compact PC for the purpose of running PICIS. It is NOT a requirement that PICIS be accessed from within the Zeus shell. There are no additional requirements for the KION software at this time.

The Sphinx is not integrated in the first release of Zeus, since the Sphinx is not currently a networked product.

This Zeus product provides a migration path for integration with the next generation front end products.

The following product solutions are planned:

1. Turnkey:
 - a. Zeus PC
 - i. Software included: Zeus CD, Prometheus ready, WebView ready, MS Works, Internet Explorer
 - b. 18" medical Grade CRT
 - c. Keyboard and pointing device
 - d. OPI and Service manual
2. Zeus PC (Patient Monitor)
 - a. Zeus PC with daughter board
 - b. OPI and Service manual
3. Zeus PC (General Purpose)
 - a. Zeus PC without daughter board (KION application)
 - b. OPI and Service Manual
4. Hardware and Software Options
5. Accessories
6. Spare Parts

5. Product Requirements

5.1. Intended Patient Populations

5.1.1. Zeus shall support the display of Real time physiological monitor from the following patient categories:

- 5.1.1.1. Adult
- 5.1.1.2. Pediatric
- 5.1.1.3. Neonatal

5.1.2. Zeus shall display the patient category of the local patient on the main display.

5.2. Languages

5.2.1. The following languages shall be supported:

- 5.2.1.1. English
- 5.2.1.2. French
- 5.2.1.3. German
- 5.2.1.4. Spanish
- 5.2.1.5. Italian

5.3. Product Integration

5.3.1. SC 7000, SC 8000, SC 9000XL

5.3.1.1. The user shall be able to display all the physiological parameters available on the SC 7000, SC 8000, And SC 9000XL. (See the Physiological Monitoring section)

5.3.2. SC 6000, SC 6002, SC 9000

5.3.2.1. The user shall be able to view SC 6000/ SC 6002/SC 9000 physiological parameters by way of the WebView application run on Zeus.

5.3.3. Network

5.3.4. The Zeus PC shall be able to connect to the following:

5.3.4.1. Infinity Network

5.3.4.2. Hospital Lan (Ethernet 10/100)

5.4. Product Configurations

5.4.1. Zeus Pick and Go Bedside (SC 7000, SC 9000XL)

This product configuration shall use the existing SC 7000 and SC 9000XL monitors as a front-end transport and add a large high-resolution display driven by the Zeus PC.

5.4.1.1. The Zeus PC shall be connected to the SC 7000 or the SC 9000XL via Ethernet.

5.4.1.2. There shall be two modes of display controlled by a video switch in the PC.

5.4.1.2.1. NT Mode: In NT mode (normal operation), the screen shall display the NT Zeus Home Screen. In this mode, control of the bedside can be from the SC 7000/9000XL or via a Zeus keyboard and pointing device.

5.4.1.2.2. Monitor Mode: If the Zeus resets, the screen shall switch to **Monitor Mode**, which shall mimic the exact display of the SC 7000/ SC 9000XL via the VGA output of the monitor. In this mode, control shall be at the local bedside only. (see Signal control section later in the specification)

5.4.2. Zeus Fixed Monitor Bedside Dual Display (SC 8000)

This product configuration shall use the existing SC 8000 monitor and display as a fixed monitor and add an additional large high-resolution display normally driven by the Zeus PC.

5.4.2.1. The Zeus PC shall be connected to the SC 8000 via Ethernet.

5.4.2.2. There shall be one mode of display:

5.4.2.2.1. NT Mode: In NT mode (normal operation), the screen shall display the NT Zeus Home Screen. In this mode, control of the bedside can be from the SC 7000/9000XL or via a Zeus keyboard and pointing device. (see Signal control section later in the specification)

5.5. Software Updates

5.5.1. Zeus Applications shall be upgraded via a laptop using CD ROM media.

5.6. Boot Sequence

5.6.1. There shall be a Fast Boot Sequence without user prompts or passwords.

5.7. Error Scheme and Recovery

5.7.1. There shall be a SW Task Manager Auto Task Restart

5.7.2. There shall be a PC Watchdog Auto Warm Start

5.7.3. There shall be a Video Switch Watchdog

5.7.4. All Fatal errors of an application shall automatically kill and restart the application.

5.8. Virus protection

5.8.1. The Zeus shall provide virus detection and cleaning for application files as well as email (Norton Anti Virus compatible with Windows NT 4.0)

5.9. Software Licensing

5.9.1. There shall be a unique serial number for each Zeus Unit (this serial number is to be used with a software Licensing scheme).

5.10. Operating System

5.10.1. The operating system on the Zeus PC shall be Windows NT 4.0 Service Pack 5 or greater.

5.11. Hardware

5.11.1. The Zeus shall contain the following Hardware and support the following Options, Accessories, Spare Parts and Service Accessories:

Hardware	Options	Accessories	Spare Parts	Service Accessories
1 Standard Mother Board and connectors	Medical Grade 18" LCD display (minimum resolution of 1280x1024)	Mount: Keyboard/pointing device	1 Siemens Monitoring Daughter Card and connectors	Laptop, CDROM connection (connects to parallel port Laptop and CDROM not supplied)
1 Siemens Monitoring Daughter Card and connectors	Medical Grade CRT display (minimum 18" with a minimum resolution of 1280x1024)	Mount: Display Wall and Desk	memory 128MB	
Board Level connectors	Keyboard/pointing device	Video Cable(if need with displays)	Hard Disk	
Battery	Power Supply	Recorder connector cover	Power Supply	
Speaker	PCI Riser Card	PC Mount Wall/Desk/IDS/SC8000	Speaker	

1 UPS (PC backup only, not intended to run the display)	Serial PCI Card	Cable Organizer	Keyboard	
1 Hard Disk	128MB memory	PigTail power cable (IDS to Zeus)	Pointing Device	
1 Chassis Case	2 nd Hard Disk		memory 128MB	
128MB memory				
512KB cache				
Power Supply	PCMCIA Type 1 cards			
Pentium Thermal Plate	Flash Card			
BIOS				
Packaging				

5.11.2. Standard Mother Board Requirements

- 5.11.2.1. This motherboard shall be a Standard PC on the Intel Embedded Roadmap
- 5.11.2.2. The motherboard Width shall be: 8.45 " or less
- 5.11.2.3. The motherboard Depth shall be: 6.67" or less
- 5.11.2.4. The motherboard shall use 94V0 UL Approved glass reinforced laminate material
- 5.11.2.5. The motherboard shall be able to run VGA independent of the daughter board
- 5.11.2.6. The motherboard shall meet the following specifications:

Board Winstone Rating	CPU	Memory/Cache	Connections	VGA	Bus Speed	Ethernet	Type	Misc.	S/W
>=28	Pentium III 400MHZ	Up to 256MB Minimum 128MB/ 512KB	-VGA Out -Serial(2) -USB(2) - Mouse/pointing device -Keyboard -Floppy/CD ROM/Printer -Power(2) -Ethernet(1)	-1600X1200 -16 Bit Color -60 Hz @ 1600X1200 Refresh 4 MB VRAM	100MHZ	10/100 Isolation according to IEC 601-1-1	Standard Mother Board	Watchdog and Watchdog NMI (Timeout Adjustable by S/W; 100 msec up to 5 sec) Unique serial number FPGA provided for PCI bus prioritization Serialized Serial EEPROM	-Full BIOS -All NT Drivers -NT 4.0 SP 5

5.11.3. Siemens Monitoring Daughter Card Requirements

- 5.11.3.1. The monitoring daughter card Width shall be: 7.10" or less
- 5.11.3.2. The monitoring daughter card Depth: 8.01" or less
- 5.11.3.3. The monitoring daughter card shall use 94V0 UL Approved glass reinforced laminate material
- 5.11.3.4. The Siemens Monitoring Daughter Card shall meet the following requirements:

Connections	Video Switch	UPS	Hub	Ethernet	Audio	Speaker	S/W	PCMCIA
-Ethernet 4 connectors, 2 Ethernet(s)	-2 to 1 -TTL Control -Tied to H/W	5 minute backup with low battery shutdown	5 ports	10/100	Sound Blaster Compatible	Full Alarm Volume > 80dB at 1 foot/Omni	-BIOS -All NT Drivers	Supports Type 1 cards

-Video In	Watchdog	shutdown			ble	foot/Omni directional		
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5.11.4. Chassis (Mechanical) Form Factor:

- 5.11.4.1. The Chassis Height shall be 3.5" or less
- 5.11.4.2. The Chassis Width shall be: 8.86" or less
- 5.11.4.3. The Chassis Depth shall be: 8.66 " or less
- 5.11.4.4. The Chassis Weight shall be: The weight of the Zeus shall be designed so as to account for the load factor of being mounted on a mounting arm or stand with an SC 7000/SC 9000XL, and IDS.
- 5.11.4.5. The Zeus PC shall be Fan-less
- 5.11.4.6. ~~The Product Label shall be: 1130~~

5.11.5. BIOS

- 5.11.5.1. There shall be a Diagnostic Mode via user input to run board level diagnostics and special configuration at startup.
- 5.11.5.2. There shall be an Indication of Disk Failure vs. Other Failure.
- 5.11.5.3. There shall be a Quick startup and warm start.
- 5.11.5.4. The BIOS shall be in a socket Flash PROM and shall be downloadable with opening the case.
- 5.11.5.5. On power up the BIOS shall boot to the first intact disk.

5.11.6. Watchdog

- 5.11.6.1. There shall be a timeout adjustable by S/W 100 msec up to 5 sec (Original Spec).

5.11.7. NMI

- 5.11.7.1. There shall be a Reset if NMI not serviced within 10 msec.
- 5.11.7.2. There shall be a Latched status to be read by S/W if Watchdog reset occurred.

5.11.8. Video Switch

- 5.11.8.1. The Zeus Defaults to Monitor Video on power up, and shall automatically switch over when the Zeus shell becomes available for display.
- 5.11.8.2. The Zeus Shell shall be displayed within 30 seconds from power up.
- 5.11.8.3. The Zeus Defaults to monitor video on any reset, and shall automatically switch over when the Zeus shell becomes available for display.
- 5.11.8.4. The Zeus Shell shall be displayed within 15 seconds from any reset.
- 5.11.8.5. There shall be a Software control to switch to monitor video or Zeus Video.

5.11.9. Hard Disk Requirements

- 5.11.9.1. There shall be two hard disks in the Zeus (second hard disk shall be optional). (Note: this shall extend the total life expectancy of the 2 ¼" disks to at least 3 years and additionally serve as a fail-safe device).
- 5.11.9.2. The Hard Disk Type shall be: IDE
- 5.11.9.3. The Hard Disk Capacity shall be: 4GB or greater.
- 5.11.9.4. The Hard Disk shall allow Shutdown when not in use.
- 5.11.9.5. The Hard Disk shall be Replaceable via a removable access plate. (Use of tools is permitted, screwdriver only).
- 5.11.9.6. In the case of a disk crash the second disk shall be mirrored to the first disk +/- one hour of data.
- 5.11.9.7. If the primary disk crashes, mechanically or electrically, upon a restart, there shall be an auto switch over by the BIOS.

- 5.11.9.8. If the primary disk crashes, due to data corruption, the user shall be able to manually switch to the second disk.

5.11.10. Power Supply Requirements

5.11.10.1. Power Input Voltage shall be within 10 to 15 Volts DC (Isolation not required from DC power; Input to Logic Voltages)

5.11.11. Environmental Specifications

5.11.11.1. Power

5.11.11.1.1. The Power Consumption shall be: approximately 20 Watts

5.11.11.2. Temperature

5.11.11.2.1. The Thermal Dissipation shall be: 15 degrees C to heat sink

5.11.11.2.2. The Cooling: Convection shall be; Internal air temperature not to exceed 20 degrees C rise external core

5.11.11.2.3. The Operating temperature shall be: 10 degrees C to 45 degrees C (50F to 95 F)

5.11.11.2.4. The Storage temperature shall be: -25 degrees C to 50 degrees C (14F to 122F)

5.11.11.3. Relative Humidity

5.11.11.3.1. Operating Humidity: 40% to 95% (non-condensing)

5.11.11.3.2. Storage Humidity: 0% to 95% (non-condensing)

5.11.11.4. Atmospheric Pressure

5.11.11.4.1. Operating Atmospheric Pressure: 525 to 795 mmHg (70 to 106 kPa)

5.11.11.4.2. Storage Atmospheric Pressure: 375 to 795 mmHg (50 to 106 kPa)

5.11.11.5. Keyboard and pointing device hygiene

5.11.11.5.1. The Keyboard and pointing device shall incorporate protection for Hygienic aspects of contamination (disinfection/sterilization).

5.12. External Connectors and Interfaces

5.12.1. The cables and connectors shall be designed so they are protected against accidental dislodging and excessive wear and tear.

	Serial	USB	Ethernet	CDROM/ Printer/Flo ppy	VGA	Keyboard/ pointing device	Audio	Power	Parallel	2 LEDs
	DB9M(2)	(2) 4 pin USB- standa rd	RJ45(5) Isolation shielding	DB25F	DB15H D (2)	6 pin DIN,P/S2 style(2)	Out, In, Mic., Mini- Jack (3)	Power Switch E/M PRT Plug PWR 2P Vert. (2) LED Siemens Part # 3376550		
Use	PICIS	Future	Infinity network -Hospital LAN MIB (future) Software Upgrade		Display			-Power	-Printer -CD ROM -Floppy Drive	Power Indicator (front), Video switch (back)

5.13. Regulatory Requirements

- 5.13.1.1. The Zeus PC shall be submitted for 510K clearance.
- 5.13.1.2. The Zeus PC shall be submitted for CE marking.
- 5.13.1.3. The Zeus PC shall be submitted for Premarket Review (Canada).
- 5.13.1.4. The Zeus PC shall be submitted for other Regulatory Clearance specific to certain countries as required.
- 5.13.1.5. The OPI shall note that the Zeus PC is not intended for Home, Aircraft, or other Ambulatory uses.

Regulatory requirements for combination of Zeus PC and Siemens supplied power supply.

5.13.2. Medical Device Safety

5.13.2.1. EN60601-1, plus Amendments 1 and 2: Medical Device Safety

The following list contains the categories within the Standard that we shall test this device under:

- 5.13.2.1.1. Patient Vicinity, no Applied Part
- 5.13.2.1.2. Spill proof (section 44.3)
- 5.13.2.1.3. Not for use in presence of flammable anesthetic gases
- 5.13.2.1.4. Class I device (metal case, line powered, with earth safety ground)

5.13.3. Medical Systems Safety

5.13.3.1. EN60601-1-1, plus Amendment 1: Medical Systems Safety

- 1500 VAC RMS Ethernet isolation (from EN60601-1-1, Amendment 1)

5.13.4. EMC Overall Standard

5.13.4.1. EN60601-1-2 EMC Overall Standard

5.13.4.1.1. EN60601-1-2 is the overall standard that specified compliance with the following EMC standards.

- 5.13.4.1.2. EN55011, Class B Electro-magnetic Radiated & Conducted Emissions
- 5.13.4.1.3. IEC801-2 ESD Susceptibility
- 5.13.4.1.4. IEC801-3 Radiated Susceptibility
- 5.13.4.1.5. IEC801-4 Fast Transient Susceptibility
- 5.13.4.1.6. IEC801-5 Fast Surge Susceptibility

5.13.5. Environmental

5.13.5.1. IEC68-2-27 Operational Shock: 50G, half-sine, 11 milliseconds

5.13.6. IEC68-2-6 Operational Vibration:

5.13.6.1. .047 double Amplitude Displacement (5 -32 Hz)

5.13.6.2. 2 G peak (32 - 500 HZ)

5.13.7. IEC68-2-31 Drop & Topple

5.13.7.1. IEC68-2-32 Free Fall: 0.5 meter (procedure 1)

5.13.7.2. NSTA, Method 1A Packaged Drop & Vibration (test methods depend on packaged weight)

5.13.8. The Zeus shall meet the following tests as required in the US:

- 5.13.8.1. Radiated Magnetic Fields (RE 101)
- 5.13.8.2. Steady State Voltage
- 5.13.8.3. Dropout
- 5.13.8.4. Slow Sag and Surge
- 5.13.8.5. Immunity Conducted Electromagnetic Energy (CS114)
- 5.13.8.6. Magnetic Field Immunity (RS101)
- 5.13.8.7. Quasi-Static Electric Fields

5.13.9. Audible noise requirements:

- 5.13.9.1. The Zeus shall be tested using a sound level meter with weighting (dBA). Less than 53 dBA when measured at a distance of 0.3 meters from all sides. Specifically, 52 dBA for white noise and 45 dBA for narrow band sounds.

5.14. Product Support and Future Expansion

- 5.14.1. Product support shall be provided for seven years on an existing board configuration from initial ship date.
- 5.14.2. There shall be an allowance in the design for an expansion slice for PCI

5.15. System Reliability

- 5.15.1. The Zeus system shall have an approximate calculated mean time between failure (MTBF) of at least 5 years with 100% duty cycle, excluding the internal battery, and hard disks.
- 5.15.2. The hard disk shall have a MTBF of at least 1-½ years with a 100% duty cycle.
- 5.15.3. There shall be an optional hard disk available to extend the MTBF of the total hard disks to 3 years with 100% duty cycle.

5.16. Mechanical Requirements

- 5.16.1. The hardware shall allow connection to a KION system.
- 5.16.2. The LED Power Indicator shall be located on the front side of the Zeus PC.
- 5.16.3. The LED Video Switch shall be located on the backside of the Zeus PC.
- 5.16.4. The Power ON/OFF button shall be located on the front side of the Zeus PC.
- 5.16.5. The device shall have a Product label on the front side of the Zeus PC.
- 5.16.6. The Zeus PC shall be a dark color in consideration of heat deflection.
- 5.16.7. There shall be the ability to mechanically disable the Video Switch (this is needed in the SC 8000 configuration)
- 5.16.8. There shall be the ability to mechanically disable the watchdog.
- 5.16.9. The PCMCIA card eject button shall be located to the right of the card slot. Note: this is consistent with the current apollo card (top).
- 5.16.10. There shall be mounting provided for the following:
 - 5.16.10.1. Zeus to IDS
 - 5.16.10.2. Zeus to Wall
 - 5.16.10.3. Zeus to Desk
 - 5.16.10.4. Zeus to SC 8000
 - 5.16.10.5. Zeus to Kion
 - 5.16.10.6. Keyboard and Pointing device to wall

5.17. Labeling

- 5.17.1. The Product label shall be located on the front side of the Zeus PC.
- 5.17.2. The Siemens Logo shall be located on the front side of the Zeus PC.
- 5.17.3. Regulatory labeling shall be located on the backside of the Zeus PC.
- 5.17.4. The Power ON/OFF button shall be labeled of the Zeus PC.
- 5.17.5. Video Switch ON/OFF shall be labeled of the Zeus PC.
- 5.17.6. Watchdog Switch ON/OFF shall be labeled of the Zeus PC.
- 5.17.7. There shall be labeling on the top surface of the Zeus informing the user NOT to obstruct the ventilation.

5.18. LEDs

- 5.18.1.1. The LED Power Indicator shall be located on the front side of the Zeus PC.
- 5.18.1.2. The LED Video Switch shall be located on the backside of the Zeus PC.

5.19. User Switches/Buttons

The Switches/buttons located on the Zeus PC base unit shall behave as follows:

Base Unit Controls

Button	Settings	Action	Location
Power	ON	<ul style="list-style-type: none"> • sounds piezo (1sec) • Turns power ON • Power LED: Green 	Front of Zeus PC (Designed in a manner that prevents accidental switching OFF of the device)
	OFF	<ul style="list-style-type: none"> • sounds piezo (6 sec) • Turns power OFF • Power LED: OFF 	
	running on UPS power	<ul style="list-style-type: none"> • Power LED: Yellow 	
Video Switch	ON	<ul style="list-style-type: none"> • Enable Video Switching mode • Video LED: Green • Display Video Switch ON icon in system tray 	Back of Zeus PC (designed in a manner that prevents accidental switching OFF)
	OFF	<ul style="list-style-type: none"> • Disable Video Switching mode • Video LED: OFF • Display Video Switch OFF icon in system tray 	

6. User Interface

6.1. Hardware

6.1.1. Keyboard

- 6.1.1.1. The keyboard shall be spill proof, drop and topple proof
- 6.1.1.2. The keyboard shall be standard QWERTY keyboard (105 keys).
- 6.1.1.3. The keyboard shall be Compatible with supported languages.
- 6.1.1.4. The keyboard shall support a replaceable cover membrane.
- 6.1.1.5. The keyboard shall be mounted so as not to become accidentally detached from support.

6.1.2. Pointing Device

- 6.1.2.1. The pointing device shall be spill proof, drop and topple proof.
- 6.1.2.2. The pointing device shall be Left hand/right hand capable.
- 6.1.2.3. The pointing device shall be mounting so as not to become accidently detached from support.
- 6.1.2.4. The pointing device shall be multi-function (minimum two button and scroll mechanism).

Note: future support of a touch screen should be considered in the user interface button size design.

6.2. Audio

- 6.2.1. There shall be graphical representation that the Audible Alarm annunciation for all parameters displayed on Zeus is OFF.
- 6.2.2. There shall not be any physiological audio in this release.

6.3. Software

- 6.3.1. The Zeus shall contain the following Software:

Standard Software	Optional Software
Windows NT 4.0 CD	Virus Software (e.g. Norton Virus)
Syngo OS	PICIS
Zeus	
WebView (Enabled)	
Prometheus (Enabled)	
Syngo Imaging (Enabled)	Microsoft Word (Future)
Microsoft Works	Microsoft Excel (Future)
Internet Explorer	
Windows Clipboard	
BIOS (see hardware section)	

* All software shall be compatible with Windows NT 4.0

6.4. Display

6.4.1. Resolution

- 6.4.1.1. The Zeus display shall be capable of displaying at least 1280 x 1024 resolution.
- 6.4.1.2. The Zeus graphical user interface shall support 1280x1024 resolution as the default resolution.
- 6.4.1.3. The Zeus graphical user interface shall support 1600 x 1200 resolution.

- 6.4.1.4. The user shall be able to set the display mode; under a Biomed menu (this is not runtime switching of display).

Note: syngo imaging supports only 1280 x 1024 mode.

6.4.2. Color

- 6.4.2.1. The Zeus display shall be capable of display at least 16 bit color mode.

- 6.4.2.2. The Zeus graphical user interface shall support 16 bit color mode.

The Zeus graphical user interface shall support 24 bit color mode at 1280x1024 resolution only.

6.5. Graphical User Interface

- 6.5.1. The Zeus shall follow the Windows NT user interface guidelines (left click, right click, function keys, copy, paste, clipboard, popups etc.).

- 6.5.2. The user shall be able to view the supported applications in their respective "full resolution up to a maximum of 1024x768 while in 1280x1024 resolution mode and 1280x1024 while in 1600x1200 resolution mode.

6.6. Zeus Shell (main display)

- 6.6.1. The Zeus Shell shall display the current Date and time and allow access to the date and time setup.

- 6.6.2. The date and time shall be displayed as DD-MMM-YYYY HH:MM.

- 6.6.3. Time shall be displayed as Military time.

- 6.6.4. The Zeus Date and time shall follow the Apollo bedside device upon connection to an Apollo and synchronized every 24 hours.

- 6.6.5. The Zeus Shell shall display an Auto Video Monitor Switch status (ON/OFF).

- 6.6.6. The Zeus Shell shall display a Watchdog status Icon (ON/OFF).

- 6.6.7. The user shall not be able to invoke the Patient View in the Zeus Shell when the Watchdog is OFF.

- 6.6.8. A message indicating the Watchdog is OFF shall be displayed on the Patient View tab informing the user how to turn the Watchdog ON.

- 6.6.9. The Zeus Shell shall display a Pointing Device Status (OK/Fault) and allow access to pointing device setup.

- 6.6.10. The Zeus Shell shall display a Device Status Icon (voltage, temp, disk) and allows access to diagnostic logs.

- 6.6.11. The Zeus Shell shall display a BioMed/Service Icon and allow access to biomed and service menu.

- 6.6.12. The Zeus Shell shall display a Windows NT mode Icon and allow access to Windows NT mode under password control.

- 6.6.13. The Zeus Shell shall present the following Task Cards:

- 6.6.13.1. Patient View

- 6.6.13.2. ECG

- 6.6.13.3. Chart
- 6.6.13.4. Imaging
- 6.6.13.5. Hospital
- 6.6.13.6. Remote View
- 6.6.13.7. Custom Tasks

Note: Requirements for each Task Card are noted in the respective sections.

- 6.6.14. The Patient View shall be the default display for the Zeus Shell.
- 6.6.15. The Patient View shall be automatically displayed within 30 seconds when the Zeus system is powered on.
- 6.6.16. The Patient View shall be automatically restarted upon the detection that it has become frozen within 30 seconds for powerup and 15 seconds for reset.
- 6.6.17. The user shall be able to configure a timeout upon which the screen shall revert back to the previous Patient View when there is no user interaction while displaying task cards other than the Patient View.
- 6.6.18. The possible Task Card timeout settings shall be: No Timeout, 1 to 60 minutes in 1 minute increments.
- 6.6.19. The default timeout for Task Cards shall be 5 minutes.
- 6.6.20. When the user switches between task cards, the applications shall be minimized, retaining their data.
- 6.6.21. During the reset time the monitor shall switch automatically to "Monitor Mode" as described previously in the Product Configurations section.

6.7. Patient View

- 6.7.1. The user shall be able to configure the Local Bed IP Address for the Zeus under service password.
- 6.7.2. Passwords shall be user configurable.
- 6.7.3. A bed shall be automatically detected as the "Local bed" when connected to the docking station configured.
- 6.7.4. ALL Data in the Patient View shall be associated with the Local Bed (only displays one patient's data).
- 6.7.5. The local bed shall have a unique/prominent graphical and textual indication.
- 6.7.6. Patient View Menu bar
 - 6.7.6.1. The Patient View Menu bar shall not be able to be covered by menus/windows in the patient view task card. (however, the Patient View Menu bar is not displayed in the other task cards). The following items are located on the Patient View menu bar:
 - 6.7.6.2. Care Unit Label
 - 6.7.6.3. Bed Label
 - 6.7.6.4. Patient Name
 - 6.7.6.5. Patient ID
 - 6.7.6.6. Patient Category
 - 6.7.6.7. Alarm Silence shall only be available when Alarm monitor is on Zeus display (monitor fixed key).

- 6.7.6.8. Alarm Limits shall only be available when Alarm monitor is on Zeus display (functions similar to the Apollo monitor fixed key with the exceptions noted below).
- 6.7.6.8.1. The user shall be able to set Alarm limits for parameters currently on display of the Apollo monitor.
- 6.7.6.8.2. Alarm limits for parameters not currently on the Apollo monitor display shall be ghosted.
- 6.7.6.9. All Alarms OFF shall only be available when Alarm monitor is on Zeus display (functions similar to the Apollo monitor fixed key).
- 6.7.6.10. CODE (functions similar to the Apollo monitor fixed key)
- 6.7.6.11. Timed Record (functions similar to the Apollo monitor fixed key)
- 6.7.6.12. Print Screen (functions similar to the Apollo monitor fixed key)
- 6.7.6.13. NBP Start/Stop (functions similar to the Apollo monitor fixed key)
- 6.7.6.14. Mark Event (functions similar to the Apollo monitor fixed key)
- 6.7.7. The user shall be able to choose to display an Alarm Monitor Window in the Patient View and Custom task cards.
- 6.7.8. The Alarm Monitor Window shall not be able to be covered by other windows.
- 6.7.8.1. The Alarm Monitor window shall mimic the parameter box, waveform and visual alarm annunciation of the Apollo Monitor (Revision VF0 level of parameter/waveform support). Note: The Zeus does not audibly annunciate alarms in the first release.
- 6.7.8.2. Updates to Home screen configuration of the SC 7000, SC 9000XL or SC 8000 shall be updated on the Alarm Monitor Window (similar to a slave display) **excluding** the following:
 - 6.7.8.2.1. 12 lead display
 - 6.7.8.2.2. All Menus
 - 6.7.8.2.3. Wedge displays
 - 6.7.8.2.4. C.O. displays
 - 6.7.8.2.5. OCRG
- 6.7.8.3. All messages displayed at the Apollo Monitor shall be displayed on the Alarm Monitor Window with their respective alarm grade behavior.
- 6.7.8.4. Zeus shall be able to display the Alarm Monitor window in 640x480 as a slave display of the SC 7000, SC 9000XL or the SC 8000.

- 6.7.9. There shall be a graphical indication to the audio Alarm setting OFF in the Alarm Monitor Window (alarm cross speaker icon).
- 6.7.10. All graphical and textual information on the SC 7000, SC 9000XL and SC 8000 shall be displayed on the Alarm Monitor Window (i.e. banners, cross bells, messages, parameters etc.).
- 6.7.11. There shall be a clear indicator for parameters that do NOT visually or audibly annunciate alarms for both the Alarm Monitor and Extended windows.
- 6.7.12. The user shall be able to revert back to the Patient View with a single action.
- 6.7.13. Waveforms, Parameters and Alarms shall have the appearance of immediate update when the user reverts back to the Patient View.
- 6.7.14. The user shall be able to configure, name and save Extended windows of parameters , Waveforms (Revision VE0 parameter and waveform support) and applications.
- 6.7.14.1. The user shall be able to select the contents of each of the windows including the following:
- 6.7.14.1.1. ALL Real Time waveforms, parameter boxes, mini trends(up to a total of 32 waveforms simultaneously between the Alarm Monitor and Extended window) available from the "Local Bed" Apollo monitor.
- 6.7.14.1.2. Show all leads (up to 12 leads) available from the Apollo monitor.
- 6.7.14.1.3. Show All Parameters Table including: MIB, EEG, KION Vent available from the Apollo monitor.
- 6.7.14.1.4. Tabular Trends available from the Apollo monitor.
- 6.7.14.1.5. Graphical Trends available from the Apollo monitor.
- 6.7.14.1.6. Lab Data, Hemo Calcs, Oxy/Vent Calcs available from the Apollo monitor.
- 6.7.14.1.7. The user shall be able to set the amount of Channels that shall be displayed in a given window for waveforms, parameters, and mini trends.
- 6.7.14.1.8. The user shall be able to assign parameter and waveform display order manually.
- 6.7.14.1.9. When set in Auto Mode, the extended window display shall follow the display/priority list order of the Apollo monitor. Updates to Home screen configuration of the Apollo Monitor shall be updated on the extended windows.
- 6.7.14.1.10. When set in Manual Mode, the user shall be able to manually configure the order of the display.
- 6.7.14.1.11. The user shall be able to configure and save, name and recall a minimum of 5 custom window layouts.
- 6.7.14.1.12. Extended Windows shall Tile when opened for display not Cascade (overlapping windows).
- 6.7.15. The following table outlines the Direct Object manipulation for Parmeter boxes for both the Alarm Monitor and Extended Windows.

Object	Mouse Over	Left click	Right click	Wheel	Tool tip
Parameter box	<ul style="list-style-type: none">outline parameter boxchange	display parameter menu in control area of task card	display context menu <ul style="list-style-type: none">Monitor controls	(may be used to increment a value with in a particular	TBD

	cursor to selection cursor		<ul style="list-style-type: none"> Parameter choices (for multi parameter pboxes) waveform size waveform choice (for multi waveform channels) Parameter menu 	selection)	
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6.7.16. Real Time Waveform Display (Alarm Monitor and Extended Windows)

Note: The Zeus does not derive the waveform data, it merely displays the data received from the Apollo monitor. See the Apollo Series Requirement Specification for details on Physiological Data Acquisition.

6.7.16.1. The maximum waveform Delay shall be 180ms

6.7.16.2. Eraser Bar mode (moving left to right)

6.7.16.3. Real Time waveforms are displayed as configured at the Apollo Monitor. The following waveform components shall be available for display:

- 6.7.16.3.1. Multiple Sweep speeds
- 6.7.16.3.2. ECG Scale
- 6.7.16.3.3. Cascade
- 6.7.16.3.4. Pacer Spikes
- 6.7.16.3.5. QRS Spikes
- 6.7.16.3.6. Resp Waveform marker (breath detect)
- 6.7.16.3.7. Signal Scales
- 6.7.16.3.8. Special Scales (overlap common scale or individual)
- 6.7.16.3.9. Grids
- 6.7.16.3.10. Clipping : waveforms shall clip to their respective channel boundaries.
- 6.7.16.3.11. Adjacent ECG waveforms shall overlap according to Apollo specifications.
- 6.7.16.3.12. Overlap: Invasive Pressures
- 6.7.16.3.13. Signal Labels
- 6.7.16.3.14. Units of Measure
- 6.7.16.3.15. 12 lead ECG display (ECG report trigger)
- 6.7.16.3.16. 1-3 ECG lead display (clipping rules)
- 6.7.16.3.17. Colors shall follow the monitor signal colors.
- 6.7.16.3.18. The user shall be able to Stop/Restart (freeze) all waveforms within an Extended window.
- 6.7.16.3.19. When waveforms are stopped, there shall be a message "Waveforms Stopped" displayed in the Extended window.
- 6.7.16.3.20. The user shall be able to configure the Stop Waveform timeout from 1 to 5 minutes in increments of 1 minute.

6.7.17. Real Time Parameter Display (Alarm Monitor and Extended Windows)

6.7.17.1. Delay: maximum of 180ms

6.7.17.2. Parameters are displayed as configured at the Apollo Monitor. The following waveform components shall be available for display and behave according to Apollo specifications:

6.7.17.2.1. Heart blip, pacer Heart blip

6.7.17.2.2. Lung blip

6.7.17.2.3. Countdown timers (continuous/interval timer NBP, TCP Gas)

6.7.17.2.4. Special Messages (READY for C.O.)

6.7.17.2.5. Units of Measure

6.7.17.2.6. Signal Labels

6.7.17.2.7. Signal Source Labels (resp)

6.7.17.2.8. Dynamic labels (Pressure labeling)

6.7.17.2.9. Special Source label switching (HR)

6.7.17.2.10. Limits

6.7.17.2.11. Crossbells

6.7.17.2.12. Alert icons

6.7.17.2.13. Date and time stamp

6.7.17.2.14. Configurable Parameter boxes (MIB, EEG, Vent, MGM)

6.7.17.2.15. Wall and Tank

6.7.17.2.16. Parameter Monitoring ON/OFF rules (Resp, C.O., O2 etc.)

6.7.17.2.17. Arrhythmia Options (Full, Basic)

6.7.17.2.18. PWP (currently in PA waveform area)

6.7.17.3. Fonts (parameter box values shall be displayed in monospaced fonts so as to avoid number shifting)

6.7.17.4. The primary parameter values displayed shall be readable from a distance of 2 meters by a person with a visual acuity of 20/20.

6.7.17.5. Colors shall follow the monitor signal colors.

6.7.17.6. Optional parameter box display (large Mean value, O2 etc.)

6.7.18. Show All Lead Display

6.7.18.1. The user shall be able to display All Available ECG leads (up to 12) from the Apollo Monitor.

6.7.18.2. The user shall be able to initiate an ECG report request to the Apollo monitor.

6.7.19. Show All Parameters (MIB, Vent, EEG)

6.7.19.1.1. The user shall be able to display the MIB, Vent and EEG show all parameter menus in the patient view.

6.7.20. FV and PV Loops

6.7.20.1. Flow-Volume loops shall be able to be displayed in real time on the main screen

6.7.20.2. Volume- Pressure loops shall be able to be displayed in real time on the main screen

6.7.20.3. The user shall be able to display one or two loops in a single extended window.

6.7.20.4. The Loop scale shall be drawn to fit the existing space (resize loop depending on extended window size and space).

- 6.7.20.5. Flow Loops are displayed as configured at the Apollo Monitor.
- 6.7.20.6. The user shall be able to display one single loop or four consecutive loop drawings (overlapping).
- 6.7.20.7. The user shall be able to save a reference loop. The last completed loop (also in 4-loop draw mode) shall be stored as the reference loop when the key "save reference" is pushed.
- 6.7.20.8. The reference loop shall be displayed with the current loop drawing(s).
- 6.7.20.9. Date and time stamp shall be displayed with reference loop.

- 6.7.21. Graphical and Tabular Trends
 - 6.7.21.1. The Graphical and Tabular Trend windows shall follow the Apollo monitor requirements for display and setup.

- 6.7.22. Lab Data
 - 6.7.22.1. The Lab Data window shall follow the Apollo Monitor requirements.


- 6.7.23. Hemo Calc
 - 6.7.23.1. The Hemodynamic Calculation window shall follow that at the Apollo Monitor requirements.

- 6.7.24. Oxy/Vent Calc
 - 6.7.24.1. The Oxy/Vent Calculations window shall follow that at the Apollo Monitor.

- 6.7.25. The following shall be displayed in the patient view when set on the Apollo Monitor:
 - 6.7.25.1. HR Alarm Banner ON/OFF
 - 6.7.25.2. Demo Software Banner
 - 6.7.25.3. Not for Patient Use
 - 6.7.25.4. ECG Banners (Filter, Pacer OFF.)
 - 6.7.25.5. Battery Status (Apollo and KION)
 - 6.7.25.6. Network messages
 - 6.7.25.7. Patient messages
 - 6.7.25.8. Standby banner
 - 6.7.25.9. Discharge banner
 - 6.7.25.10. Privacy Mode
 - 6.7.25.11. Offline banner (message)
 - 6.7.25.12. Patient Admit (available through Prometheus – keyboard entry, send to monitor)

- 6.7.26. Simulated Display Data
 - 6.7.26.1. They user shall be able to display simulated data from the Apollo monitor in the Alarm Monitor window.
 - 6.7.26.2. Simulated Display Data shall be clearly marked.

- 6.7.27. Pick and Go
 - 6.7.27.1. If the monitor becomes undocked the message " Bed Disconnected" shall be displayed on the Zeus in the Alarm Monitor window, and shall be removed when the Monitor becomes available (It is desired that the messages indicate a pick and go as "Monitor Undocked")

- 6.7.28. New patient
 - 6.7.28.1. The Zeus shall detect when a new "Local" patient is connected/docked.
 - 6.7.28.2. When a new patient is detected the following shall occur:
 - 6.7.28.2.1. 

6.7.29. Monitor Disconnected (communication interrupted)

- 6.7.29.1. If the monitor goes off line the message "Bed Offline" shall be displayed on the Zeus and shall be removed when the Monitor becomes available.

6.8. Display Scales and Ranges

6.8.1. The following parameter scales and ranges shall be available for display from the Apollo monitor:

Ranges (lower/upper)		Patient Category								
Parameter	Units	Adult			Pediatric			Neonatal		
		Trend Scales	Alarm Limits, Incr	Wavefor m Scales	Trend Scales	Alarm Limits, Incr	Wavefor m Scales	Trend Scales	Alarm Limits, Incr	Wavefor m Scales
ECG	mV/cm	N/A	N/A	0.25, 0.5, 1, 2, 4, 8	N/A	N/A	0.25, 0.5, 1, 2, 4, 8	N/A	N/A	0.25, 0.5, 1, 2, 4, 8
HR	bpm	0/300, +10	20/300, +5	N/A	0/300, +10	20/300, +5	N/A	0/300, +10	20/300, +5	N/A
PVC	PVC/min	0/60	0/50, +1 (upper)	N/A	0/60, +10	0/50, +1	N/A	N/A	N/A	N/A
%Paced	%	0/100, +10	n/a	n/a	0/100, +10	n/a	n/a	n/a	n/a	n/a
ST	mm	-15/15, +1	-15/15, +0.1	n/a	-15/15, +1	-15/15, +0.1	n/a	n/a	n/a	n/a
	mV	-1.5/1.5, +0.1	-1.5/1.5, +0.01	n/a	-1.5/1.5, +0.1	-1.5/1.5, +0.01	n/a	n/a	n/a	n/a
SpO2	%	50/100, +5	20/100, +1	10/100, % (size) +10	50/100, +5	20/100, +1	10/100, % (size) +10	50/100, +5	20/100, +1	10/100, % (size) +10
PLS	bpm	0/300, +10	30/300, +5	n/a	0/300, +10	30/300, +5	n/a	0/300, +10	30/300, +5	n/a
ART S/ M/D	mmHg	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300
	kPa	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40
PA S/M/D	mmHg	-5/120, +5	-5/120, +1	0:25,40,5 0,75,100, 150	-5/120, +5	-5/120, +1	0:25, 40, 50, 75, 100, 150	-5/120, +5	-5/120, +1	0:25,40, 50,75,10 0,150
	kPa	-1/16, +1	-0.6/16, +0.1	0:4,6,8, 12,16,20	-1/16, +1	-0.6/16, +0.1	0:4,6,8, 12,16,20	-1/16, +1	-0.6/16, +0.1	0:4,6,8, 12,16,20
CVP	mmHg	-5/120, +5	-5/120, +1	-5:10, 20, 30, 40, 50	-5/120, +5	-5/120, +1	-5:10, 20, 30, 40, 50	-5/120, +5	-5/120, +1	-5:10, 20, 30, 40, 50
	kPa	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8
RV S/M/D	mmHg	-5/120, +5	-5/120, +1	0:25,40,5 0,75,100, 150	-5/120, +5	-5/120, +1	0:25, 40, 50, 75, 100, 150	-5/120, +5	-5/120, +1	0:25,40, 50,75,10 0,150
	kPa	-1/16, +1	-0.6/16, +0.1	0:4,6,8	-1/16, +1	-0.6/16, +0.1	0:4,6,8	-1/16, +1	-0.6/16, +0.1	0:4,6,8

				12,16,20			12,16,20			12,16,20
RA	mmHg	-5/120, +5	-5/120, +1	-5: 10, 20,30, 40, 50	-5/120, 5	-5/120, +1	-5:10, 20, 30, 40, 50	-5/120, +5	-5/120, +1	-5:10, 20, 30, 40, 50
	kPa	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8
LA	mmHg	-5/120, +5	-5/120, +1	-5:10, 20, 30, 40, 50	-5/120, +5	-5/120, +1	-5:10, 20, 30, 40, 50	-5/120, +5	-5/120, +1	-5:10, 20, 30, 40, 50
	kPa	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8	-1/16, +1	-0.6/16, +0.1	-1:2, 4,5,6,8
LV S/ M/D	mmHg	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300
	kPa	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40
NBP S/ M/D	mmHg	0/250, +10	10/250, +1	n/a	0/250, +10	10/170, +1	n/a	0/150, +10	10/130, +1	n/a
	kPa	0/35, +1	1.5/33.3, +0.1	n/a	0/35, +1	1.5/23, +0.1	n/a	0/20, +1	1.5/17, +0.1	n/a
CPP	mmHg	-5/300, +1	-5/300, +1	n/a	-5/300, +1	-5/300, +1	n/a	-5/300, +1	-5/300, +1	n/a
	kPa	-1/40, +0.1	-0.6/40, +0.1	n/a	-1/40, +0.1	-0.6/40, +0.1	n/a	-1/40, +0.1	-0.6/40, +0.1	n/a
ICP	mmHg	-5/120, +1	-5/120, +1	0:5, 10, 15,20,50, 100	-5/120, +1	-5/120, +1	0:5, 10, 15,20,50, 100	-5/120, +1	-5/120, +1	0:5, 10, 15,20,50, 100
	kPa	-1/16, +0.1	-0.6/16, +0.1	0:1,2,3,4, 8,16	-1/16, +0.1	-0.6/16, +0.1	0:1,2,3,4, 8,16	-1/16, +0.1	-0.6/16, +0.1	0:1,2,3,4, 8,16
PWP	mmHg	-5/120, +5	n/a	n/a	-5/120, +5	n/a	n/a	-5/120, +5	n/a	n/a
	kPa	-1/16, +1	n/a	n/a	-1/16, +1	n/a	n/a	-1/16, +1	n/a	n/a
GP's S/ M/D	mmHg	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300	-5/300, +5	-5/300, +1	0:50, 75, 100,150, 200,250, 300
	kPa	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40	-1/40, +1	-0.6/40, +0.1	0:8, 12,16,20, 24,32,40
Resp	RPM	0/100, +10	5/100, +1	5/100, (size) +5%	0/100, +10	5/145, +1	5/100, (size) +5%	0/100, +10	5/145, +1	5/100, (size) +5%
tpO2	mmHg	0/300, +10	10/300, +1	n/a	0/300, +10	10/300, +1	n/a	0/300, +10	10/300, +1	n/a
tpO2*	kPa	0/40, +1	2.5/40, +0.1	n/a	0/40, +1	2.5/40, +0.1	n/a	0/40, +1	2.5/40, +0.1	n/a
tpCO2	mmHg	0/150, +10	10/150, +1	n/a	0/150, +10	10/150, +1	n/a	0/150, +10	10/150, +1	n/a
tpCO2*										

	kPa	0/20, +1	2.5/20, +0.1	n/a	0/20, +1	2.5/20, +0.1	n/a	0/20, +1	2.5/20, +0.1	n/a
et HAL	%	0/20, +1	0/7.5, +0.1	0:1,2,3,5,10,20	0/20, +1	0/7.5, +0.1	0:1, 2, 5, 10, 20	0/20, +1	0/7.5, +0.1	0:1,2,3,5,10,20
et HAL	%		0/7.5, +0.1			0/7.5, +0.1			0/7.5, +0.1	
et SEV	%	0/80, +1	0/9, +0.1		0/80, +1	0/9.0, +0.1		0/80, +1	0/9, +0.1	
et SEV	%		0/9, +0.1			0/9.0, +0.1			0/9, +0.1	
et ISO	%	0/40, +1	0/7.5, +0.1		0/40, +1	0/7.5, +0.1		0/40, +1	0/7.5, +0.1	
et ISO	%		0/7.5, +0.1			0/7.5, +0.1			0/7.5, +0.1	
et ENF	%	0/40, +1	0/7.5, +0.1		0/40, +1	0/7.5, +0.1		0/40.0, +1	0/7.5, +0.1	
et ENF	%		0/7.5, +0.1			0/7.5, +0.1			0/7.5, +0.1	
et DES	%	0/100, +1	0/20, +0.5		0/100, +1	0/20, +0.5		0/100, +1	0/20, +0.5	
et DES	%		0/20, +0.5			0/20, +0.5			0/20, +0.5	
et O2	%	0/100, +10	10/100, +1	20:50, 100	0/100, +10	10/100, +1	20:50, 100	0/100, +10	10/100, +1	20:50, 100
et O2	%	0/100, +10	18/100, +1		0/100, +10	18/100, +1		0/100, +10	18/100, +1	
et FIO2	%	10/100, +10	18/100, +1	n/a	10/100, +10	18/100, +1	n/a	10/100, +10	18/100, +1	n/a
et CO2, et CO2*	mmHg	0/95, +5	5/95, +1	0:40, 60, 80	0/95, +5	5/95, +1	0:40, 60, 80	0/95, +5	5/95, +1	0:40, 60, 80
	kPa	0/12.5, +0.5	0.7/12.6, +0.1	0:5, 8, 12	0/12.5, +0.5	0.7/12.6, +0.1	0:5, 8, 12	0/12.5, +0.5	0.7/12.6, +0.1	0:5, 8, 12
	%	0/12, +0.5	0.7/17.6, +0.1	0:5, 8, 12	0/12, +0.5	0.7/17.6, +0.1	0:5, 8, 12	0/12, +0.5	0.7/17.6, +0.1	0:5, 8, 12
et CO2, et CO2*	mmHg	0/10, +1	2:10, +1 (upper)	same as et CO2	0/10, +1	2:10, +1 (upper)	0:40, 60, 80	0/10, +1	2:10, +1 (upper)	same as et CO2
	kPa	0/2, +0.1	0.3/1.3, +0.1 (upper)		0/2, +0.1	0.3/1.3, +0.1 (upper)	0:5, 8, 12	0/2, +0.1	0.3/1.3, +0.1 (upper)	
	%	0/2, +0.1	0.3/1.8, +0.1 (upper)		0/2, +0.1	0.3/1.8, +0.1 (upper)	0:5, 8, 12	0/2, +0.1	0.3/1.8, +0.1 (upper)	
et RRc	breaths/ min	0/100, +5	5/90, +1	n/a	0/100, +5	5/90, +1	n/a	0/100, +5	5/90, +1	n/a
et RRc*										
et RRc	breaths/ min	0/140, +10	5/145, +1	n/a	0/140, +10	5/145, +1	n/a	0/140, +10	5/145, +1	n/a
et rms co2										
et RRV	breaths/ min	0/75, +5	n/a	n/a	0/75, 5	n/a	n/a	0/75, +5	n/a	n/a
et C.O	L/min	0/10, +1	n/a	n/a	0/10, +1	n/a	n/a	n/a	n/a	n/a
et T a/b	C	-5/50, +0.5	-5/50, +0.1	n/a	-5/50, +0.5	-5/50, +0.1	n/a	-5/50, +0.5	-5/50, +0.1	n/a
et Temp										
	F	25/120, +1	25/120, +1	n/a	25/120, +1	25/120, +1	n/a	25/120, +1	25/120, +1	n/a
et BT	C	-5/50, +5	25/43, +0.1	n/a	-5/50, +5	25/43, +0.1	n/a	n/a	n/a	n/a
et BT*										
	F	25/120, +1	77/109, +1	n/a	25/120, +1	77/109, +1	n/a	n/a	n/a	n/a
et delta T	C	n/a	0/55, +0.1	n/a	n/a	0/55, +0.1	n/a	n/a	0/55, +0.1	n/a
	F	n/a	0/95, +1	n/a	n/a	0/95, +1	n/a	n/a	0/95, +1	n/a

SvO2	%	50/100, +5	n/a	n/a	50/100, +5	n/a	n/a	50/100, +5	n/a	n/a
SaO2	%	50/100, +5	n/a	n/a	50/100, +5	n/a	n/a	50/100, +5	n/a	n/a
CCO	L/min	0/10, +1	n/a	n/a	0/10, +1	n/a	n/a	0/10, +1	n/a	n/a
CCI	L/min/m2	0/5, +1	n/a	n/a	0/5, +1	n/a	n/a	0/5, +1	n/a	n/a
ICI	L/min/m2	0/5, +1	n/a	n/a	0/5, +1	n/a	n/a	0/5, +1	n/a	n/a
ICO	L/min	0/10, +1	n/a	n/a	0/10, +1	n/a	n/a	0/10, +1	n/a	n/a
SVR	Dyne/s/ cm-5	0/4000, +100	n/a	n/a	0/4000, 100	n/a	n/a	0/4000, +100	n/a	n/a
SVRI	Dyne/s/ cm-5/m2	0/5000, +100	n/a	n/a	0/5000, +100	n/a	n/a	0/5000, +100	n/a	n/a
DO2	ml/min	0/1000, +50	n/a	n/a	0/1000, +10	n/a	n/a	0/1000, +50	n/a	n/a
VO2	ml/min	0/300, +10	n/a	n/a	0/300, +10	n/a	n/a	0/300, +10	n/a	n/a
PIP	cmH2O	0/100, +5	n/a	n/a	0/100, +5	n/a	n/a	0/100, +5	n/a	n/a
PEEP	cmH2O	0/50, +5	n/a	n/a	0/50, +5	n/a	n/a	0/50, +5	n/a	n/a
MAP	cmH2O	0/50, +5	n/a	n/a	0/50, +5	n/a	n/a	0/50, +5	n/a	n/a
MVe	L/min	0/25, +0.5	n/a	n/a	0/25, +0.5	n/a	n/a	0/25, +0.5	n/a	n/a
MVi	L/min	0/25, +0.5	n/a	n/a	0/25, +0.5	n/a	n/a	0/25, +0.5	n/a	n/a
TVe	ml	0/1500, +100	n/a	n/a	0/1500, +100	n/a	n/a	0/50, +1	n/a	n/a
TVI	ml	0/1500, +100	n/a	n/a	0/1500, +100	n/a	n/a	0/50, +1	n/a	n/a
Paw	cmH2O	n/a	n/a	-5:25, -10:50, -20:120	n/a	n/a	-5:25, -10:50, -20:120	n/a	n/a	-5:25, -10:50, -20:120
Vol	ml	n/a	n/a	50, 100, 250,500, 1000	n/a	n/a	50, 100, 250,500, 1000	n/a	n/a	50, 100, 250,500, 1000
Flow	L/min	n/a	n/a	-5:5, -10:10, -20:20, -50:50, -100:100 -200:200	n/a	n/a	-5:5, -10:10, -20:20, -50:50, -100:100 -200:200	n/a	n/a	-5:5, -10:10, -20:20, -50:50, -100:100 -200:200
EEG (1-4)	micro V	n/a	n/a	-5:5, -10:10, -25:25, -50:50, -100:100 -250:250 -500:500	n/a	n/a	-5:5, -10:10, -25:25, -50:50, -100:100 -250:250 -500:500	n/a	n/a	-5:5, -10:10, -25:25, -50:50, -100:100 -250:250 -500:500
MED	Hz	0/30, +1	n/a	n/a	0/30, +1	n/a	n/a	0/30, +1	n/a	n/a
SEF	Hz	0/30, +1	n/a	n/a	0/30, +1	n/a	n/a	0/30, +1	n/a	n/a
BSR	%	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a
Pwr	%	40/100, +1	n/a	n/a	40/100, +1	n/a	n/a	40/100, +1	n/a	n/a
Alph	%	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a

Beta	%	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a
Theta	%	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a
Delta	%	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a	0/100, +1	n/a	n/a

6.9. Parameter Signal Control

6.9.1. Adjusting signal control settings on the Zeus shall update the settings on the Apollo monitor as well.

6.9.2. The following Parameter signal control shall be available from the Patient View for the Local Patient:

ECG <i>*Show All Leads</i> Size ECG Lead Setup ECG Options Brady Detection HR Source QRS/ARR Select *ST Monitoring *ARR Monitoring *RESP Monitoring *Relearn	Size ECG Size All ECG Channel 1 Size Channel 2 Size Channel 3 Size	Lead Setup *ECG Channels <i>Channel 1</i> <i>Channel 2</i> <i>Channel 3</i> 12 Lead Position	ECG Options Filter Artifact Rejection Pacer Detect QRS Sync Marker Pulse Tone Source *Pulse Tone Volume *ECG Report Setup
	<i>Show All Leads</i> <i>More</i> <i>Report</i>	ARR Setup *Relearn List of Arrhythmia calls. *ARR Monitoring (Table: Alarm; Rate; Count; Archive)	
ST Menu ST Monitoring ST Lead 1 ST Lead 2 ST Lead 3 ST Mini Trend Relearn *Show All Leads *ST Alarm Setup	<i>Show All Leads</i> <i>More</i> <i>Report</i>	ST Alarm setup Auto Set List of ST Parameters More Event Duration Relearn	
ART/IBP Zero Scale Filter Cal Factor Last Cal Factor Manometer Cal Pressure Overlap Common Scale *Pressure Labels	MIB: SvO2 Show All Parameters <i>Parameter 1</i> <i>Parameter 2</i> <i>Parameter 3</i> SvO2 Mini Trend	Paw/Vol Show All Parameters Pressure Scale Flow Scale Split Screen Loop Draw Clear Reference Vol Mini Trend	TEMP (1-3) TEMP Display
NBP Interval Time Continuous Mode Inflation Limit Calibrate Mode	SpO2 Pulse Tone Source *Pulse Tone Volume Waveform Size Averaging	etCO2 Sensor Cal. Adapter Cal. N2O Compensation O2 Compensation Scale Atm. Pressure Mode Atm. Pressure Averaging Measurement Mode Respiration Filter RRc Apnea Time	C.O. Catheter Type Catheter Size Injectate Volume Comp. Constant Mode C.O. Start

			Comp.Constant (workspace) Keypad Backspace Accept Cancel
Agent ScaleDi Agent Display Sample Flow Rate ID OverrideL Auto Zero Delay	O2 MultiGas Parameter O2 Scale N2O Display Sample Flow Rate Auto Zero Delay 1 Point Cal. 2 Point Cal. Last O2 Cal.	etCO2* (MGM) Scale Agent Display Sample Flow Rate Pressure Comp. RRc* Apnea Time Auto Zero Delay	
MultiGas Waveform MultiGas Parameter O2 Scale N2O Display Agent Display Agent Scale ID Override Sample Flow Rate Auto Zero Delay 1 Point Cal. 2 Point Cal. Last O2 Cal.	N2O O2 Scale Sample Flow Rate N2O Display MultiGas Parameter Auto Zero Delay 1 Point Cal. 2 Point Cal. Last O2 Cal.	RESP RESP LeadL Mode Size RESP Marker Coincidence Detect *RESP Monitoring Apnea Time Relearn	tpO2/CO2 Site Timer Set Temp Start Calibration Stop Calibration Correction Factors Atm. Pressure Mode Auto Pressure Manual Pressure tpO2/CO2* Site Timer Set Temp Start Calibration Stop Calibration Correction Factors Atm. Pressure Mode Auto Pressure Manual Pressure
FiO2 1 point Cal. 2 point Cal. Last O2 Cal	Wall And Tank Split Screen Loop Draw Clear Reference	EEG (1-4) Lead Label Size Size all EEG Channels Parameter 1 Parameter 2 Parameter 3 EEG Mini Trend SEF Setting Power Spectra Check Impedance	
Alarm Limits (the Alarm Limit settings shall be integrated into each of the individual parameter menus)	ST Auto Set List of ST Parameters More Event Duration Relearn	ARR *Relearn List of Arrhythmia calls. *ARR Monitoring D (Table: Alarm; Rate; Count; Archive)	

6.9.2.1. Signal control menus shall not cover the extended windows by default.

6.9.3. Clinical Rounds Displays

6.9.3.1. The user shall be able to create, save, name up to 10 user customizable views to be displayed on the Patient View Task Card.

6.9.3.2. The user shall be able to transfer the saved customizable views to another Zeus.

6.10. Condensed Bed

6.10.1. Each task card shall have a region to display an alarm message from the Apollo.

6.10.2. There shall be a visual indication of an Apollo alarm on the current task card.

6.11. Chart

6.11.1. Trends

The user shall be able to view Graphical and Tabular Trends from within the Chart Task card

6.11.2. Prometheus

6.11.2.1. Zeus shall be compatible with the First release of Prometheus.

6.11.2.2. The user shall be able to run the Prometheus Chart Task card.

6.12. Images

6.12.1. Syngo Imaging

6.12.1.1. The user shall be able to run the Syngo Imaging program Rev VA50A from within Zeus.

6.13. Hospital

6.13.1. The user shall be able to run Internet Explorer 5.0 from within Zeus to connect to the Hospital Intranet.

6.14. Remote View

6.14.1. The user shall be able to launch up to 4 WebView applications (Rev VE0 or greater) to serve as remote views of other patients.

6.14.2. The user shall be able to Silence Alarms for a Remote Bed.

6.14.3. There shall be a notification to the user when there is an alarm at a displayed Remote Bed.

6.14.4. There shall be a clear graphical indication of the Remote Bed to distinguish it from the local bed.

Note: The WebView application is not intended to function similar to a Extended Monitor Window of a bedside. There shall not be any video switching mode with beds displayed within WebView if NT should fail.

6.15. Custom Tasks

6.15.1. The user shall be able to create, save, name up to 10 Custom Task views to be displayed on the Custom Tasks Card.

6.15.2. The user shall be able to transfer the saved customizable views to another Zeus.

6.15.3. The user shall be able to access the following additional applications:

- Microsoft Works – Windows NT 4.0 compatible

6.15.4. X Terminal Support

6.15.4.1. Zeus shall be compatible with the Windows NT 4.0 compatible Xterminal.

6.15.4.2. The user shall be able to run an Xterminal from within Zeus.

6.15.5. Web Browser

6.15.5.1. Zeus shall be compatible with Internet Explorer 5.0.

6.15.5.2. The user shall be able to run Internet Explorer from within Zeus.

6.15.5.3.

6.16. Online Help resources

6.16.1.1. The user shall be able to access an online quick guide with the following:

6.16.1.1.1. Provide an overall description of the Zeus program (general operating instructions).

6.16.1.1.2. Explain how to perform specific tasks

6.16.1.1.3. Clarify the significance of choices in menus

6.16.1.1.4. Indicate what to do next when user encounters error messages

6.16.1.1.5. Allow the user to look at the program while reading Help

6.16.1.1.6. Context sensitive (i.e. The help icon on the Remote view tab shall "link the user to help related to Remote View)

6.16.1.1.7. Table of contents

6.16.1.1.8. Index of topics

6.16.1.1.9. Search for a particular topic (Find)

6.16.1.2. The user shall be able to access an online quick guide with specific instructions for the SC 7000, SC 8000, and SC 9000XL.(Apollo series). The quick guide for the Apollo series shall contain the following:

6.16.1.2.1. General Operating instructions SC 7000

6.16.1.2.2. General Operating instructions SC 8000

6.16.1.2.3. General Operating instructions SC 9000XL

6.16.2. The Zeus shall support "Button Help" or tool tips.

6.17. Operators Instruction Manual

6.17.1. There shall be a printed Operators Instruction manual available in the supported languages.

6.18. Service Manual

6.18.1. There shall be a printed Service Manual available in supported languages.

6.19. Windows NT Desktop

- 6.19.1. The user shall be able to access the Windows NT desktop.
- 6.19.2. When the user accesses the Windows NT desktop the Zeus Shell application shall be terminated and an entry of this made in the logs.
- 6.19.3. A confirmation popup shall be displayed when switching from the Zeus Shell to the Windows NT desktop allowing the user to cancel or continue and informing the user that the Zeus Shell application shall be to be shut down if they continue.
- 6.19.4. The default selection on the Zeus Shell shutdown confirmation popup shall be Cancel.
- 6.19.5. The user shall be able to invoke the Zeus Shell from the Windows NT desktop (similar to standard windows programs).
- 6.19.6. System shutdown from the Windows NT desktop follows standard windows behavior.

6.20. Health Monitor

- 6.20.1. The Health Monitor component shall be implemented as part of the Zeus system.
- 6.20.2. The Extended Monitor application has real-time requirements for data display from the locally attached devices. Other applications shall not be allowed to interfere with the Extended Monitor's execution by consuming too much system resources like memory, disk space, etc. Any offending application shall be terminated.
- 6.20.3. Any time an application is terminated by the Health Monitor a log record about this shall be added to Windows Event Log and a system-wide informational modal dialog box shall be flashed for 10 seconds or until it is dismissed by the user, whatever comes first.
- 6.20.4. If one of the Zeus components' application crashes or becomes unresponsive, the Health Monitor shall attempt to auto-correct the problem. If possible, the faulty application has to be re-launched, otherwise, the whole computer should be restarted.
- 6.20.5. New types of performance/reliability checks and new types of objects to be checked should be added transparently, without the need to modify existing components of Health Monitor.
- 6.20.6. When Health Monitor application makes decision about terminating a process, it shall take into account relative priorities of processes. First it shall attempt to kill processes from groups with lower priorities, as defined in the list below.
- 6.20.7. Group priorities are decreasing toward the bottom of the list.

Figure 2: Zeus System's Groups

Group Name	Group Members
System	Windows system processes
Zeus Critical	Health Monitor, Watchdog, Zeus Shell

Zeus Views	Extended Monitor applications, Waveforms
Zeus Menus	Menus
Zeus Non RT	Other Non-RT Zeus components
Medical	Non-Zeus medical applications
Non-Medical	Any other application

6.21. Client interaction

- 6.21.1. The Health Monitor component shall not have user interface.
- 6.21.2. Authorized shall be able to configure the component's runtime behavior by modifying its Registry parameters via GUI interface.
- 6.21.3. The Health Monitor application shall be able to run either as a Windows NT service, or as a stand-alone application, as determined by the Registry settings.

6.22. System Requirements

- 6.22.1. The Health Monitor component shall read its runtime settings from Registry upon start-up, and change its behavior accordingly.
- 6.22.2. New components of the Health Monitor application, once registered, shall be picked up by the application next time it is run.
- 6.22.3. Health Monitor Zeus monitoring shall be started by the Zeus shell after the Zeus system is started, and it shall operate in the background for as long as Zeus is running. Shutdown sequence shall be the opposite – Health Monitor shall be terminated prior to terminating any other Zeus components.
- 6.22.4. Health Monitor shall conduct continuous monitoring of the following parameters:
 - 6.22.4.1. Network status
 - 6.22.4.2. CPU chip temperature
 - 6.22.4.3. Input voltage from the power source
 - 6.22.4.4. Disk spinning time, in hr:min:sec
- 6.22.5. Those measurements shall be taken periodically from the moment Health Monitor service starts up.
- 6.22.6. They should stay within defined configurable limits. If these measurements are outside of these limits, an error log record shall be made in the Windows Event Log that can be viewed later.
- 6.22.7. Health Monitor functionality shall have a configurable Enable/Disable switch in Registry.
- 6.22.8. Health Monitor application shall fit in the following resource usage limits:
 - 6.22.8.1. Memory - 500K
 - 6.22.8.2. Disk activity - shall not cause any significant disk I/O after startup (some small amount of I/O may be necessary due to Windows internal operations).
 - 6.22.8.3. CPU load - shall not cause overall CPU load to increase by more than 5% for the period of time greater than 1 minute in a row.

6.22.9. Common Windows NT Performance Monitor Scenarios

6.22.9.1. When monitoring Zeus system and the operating system to investigate performance-related issues, there are three main areas on which to concentrate initial efforts:

- Disk activity
- Processor utilization
- Memory usage

6.22.9.2. It can be useful to monitor Microsoft Windows NT® and Zeus counters at the same time to determine any correlation between the performance of Zeus and Windows NT. For example, monitoring the Windows NT disk I/O counters and the Zeus Buffer Manager counters at the same time can show how the whole system is behaving.

6.22.9.3. Monitoring a computer using Health Monitor can slightly impact the performance of the computer being monitored. Monitoring too many counters adds overhead to the monitoring process and shall affect the computer being monitored, possibly affecting the results produced. Therefore, only most important counters should be monitored. Alternatively, the Health Monitor service can be configured to run remotely.

6.23. Specific Measurements

6.23.1.1. Zeus components may have special quota, higher than that of ordinary processes. This configurable parameter can be set in Registry.

6.23.2. All of the parameters listed below shall be configurable via Registry settings. See section 4.3.7.1 for the complete list.

6.23.3. All parameters listed in this section shall be applicable to the whole system - there shall be no per-process configuration.

6.23.4. Each of the checks types listed below shall be able to be Enabled/Disabled separately by using Registry switches.

6.23.5. The following types of checks shall be implemented with this release of Health Monitor:

Zeus resource checks:

6.23.6. By default, in case of failures any action shall be taken after 3 retries 20 seconds apart each.

Figure 3: Zeus Resource Monitor Checks

Specific Check	Failure Parameters	Failure Action
Check that all Zeus applications (list shall be configurable) are running.	A necessary Zeus component application is not running.	Health Monitor should attempt to launch it, and a log record shall be added to the Windows Event Log.
	A necessary Zeus application failed to launch 3 times (exact number shall be a configurable parameter in the Registry).	The computer is restarted.
RTView's Page Fault count. Explanation: if this number is growing, then the system's	This Page Fault count is above a certain threshold (configurable in Registry).	An attempt shall be made to increase Working Set of RTView and to empty Working Sets of all non-essential

memory is too heavily loaded.		Sets of all non-essential applications.
	If RTView's Page Fault count is still above the threshold.	All non-essential applications shall be terminated in turn, until Page Fault shall return to normal or there are no more of those applications.

System resource checks:

6.23.7. In case of failures any action shall be taken after 3 retries 20 seconds apart each.

Figure4: System Resource Monitor Checks

Specific Check	Check Explanation	Failure Parameters	Failure Action
Total Processor Usage	Too high usage shall lead to overall system unresponsiveness. Note that if using a multiprocessor computer, " System: Total Processor Time " and " Processor: Processor Time " for each processor may be monitored separately.	Over 80%	All non-essential applications shall be terminated in turn.
Processor Queue Length	Sustained count of 2 or greater indicates processor congestion	Sustained count of 2 or greater lasts longer than 5 minutes (configurable parameter).	All non-essential applications shall be terminated in turn.
Available Memory	The Available Bytes counter indicates how many bytes of memory are currently available for use by processes. Low values for the Available Bytes counter can indicate that there is an overall shortage of memory on the computer or that an application is not releasing memory.	Available memory is below a configurable threshold.	An attempt shall be made to force all non-essential processes to be paged out. If that does not help, all non-essential applications shall be terminated in turn.
Paging Rate	The Pages/sec counter indicates the number of pages that either were retrieved from disk due to hard page faults or written to disk to free space in the working set due to page faults. A high rate for the Pages/sec counter could indicate excessive paging. Monitor the Memory: Page Faults/sec counter to make sure that the disk	Hard disk paging rate is too high (a configurable parameter).	An attempt shall be made to force all non-essential processes to be paged out. If that does not help, all non-essential applications shall be terminated in turn.

	activity is not caused by paging.		turn.
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Computer resource checks:

6.23.8. In all cases beside the "Disk Usage" counter, actions shall be repeated with 1-minute intervals.

Figure 5: Computer Resource Monitor Checks

Specific Check	Check Explanation	Failure Parameters	Failure Action
Network status.	Ping time shows the rate of data exchange on the network. If a ping times out, it means that the connection is broken or unacceptably slow.	Ping time is longer than a configured interval.	A high-priority notification is sent to the system-wide Notification component.
CPU chip temperature.	Chip temperature raising too high indicates malfunctioning in the CPU cooling system and may lead to processor damage and random data displayed.	The temperature is above a configured threshold.	A medium-priority notification is sent to the system-wide Notification component.
Input voltage from the power source.	Voltage outside of the standard range shall lead to the partial or complete system shutdown. Wild power fluctuation may be indicative of power source's failure.	Voltage is outside of configurable limits.	A medium-priority notification is sent to the system-wide Notification component.
Hard disk spinning time.	Hard disk has a usage limit documented by the manufacturer. When its spinning time approaches the configured limit, hard disk's service may be needed to prevent failures.	Disk spinning time exceeds a configurable period.	A single low-priority notification is sent to the system-wide Notification component.
An important logical hard disk's partition is low on space	Either Windows partition, or Zeus partition (if it is not installed on the Windows partition) of hard disk is nearing its capacity. Some data has to be removed from the partition.	The partition is over 80% full.	A high-priority notification is sent to the system-wide Notification component.

Each process' resource checks

6.23.9. In case of failures any action shall be taken after 3 retries 20 seconds apart each.

6.23.10. Each check shall be applied to each process in turn (with the exception of Windows system processes).

Figure 6: Processes' Resource Monitor Checks

Specific Check	Check Explanation	Failure Parameters	Failure Action
Handle count	The process is probably leaking handles.	Handle count reaches a threshold level (configurable parameter) and keeps steadily increasing after that.	The process shall be terminated.
Working Set size	The process is probably leaking memory or allocating excessive amounts of memory.	The Working Set reaches a threshold level (configurable parameter).	An attempt shall be made to empty it. If the Working Set could not be emptied or is still above the threshold, the process shall be terminated.
Verify responsiveness of processes with GUI	Responsiveness means that the process has retrieved messages from its message queue recently. If it has not, it is probably hung up.	The process has retrieved messages from its message queue within last 10 seconds (configurable parameter).	The process shall be terminated.
CPU load	If a process consistently spends large percentage of process's time to execute processor instructions, it is probably running a busy loop.	The process consistently consumes over 90% of process's time to execute processor instructions.	The process shall be terminated.

6.23.11. Before a process is terminated, its group affiliation shall be checked.

6.23.12. In case of multiple failures of a system-critical process (see the configurable parameter above) the computer shall be restarted instead of just terminating the process. The table below summarizes this behavior as it applies to the group defined earlier.

Figure 7: Zeus Groups' Failure Actions

Process' Group Name	Action
System	Not checked – no action
Zeus Critical	Computer warm-reboot
Zeus RT	Computer warm-reboot
Zeus Views	Terminate Process
Zeus Menus	Terminate Process
Zeus Non RT	Terminate Process
Medical	Terminate Process

Non-Medical	Terminate Process
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6.24. PICIS

6.24.1. Zeus shall be compatible with the Care Suite 6.0 version of PICIS.

Note: It is not a requirement to run PICIS from within the Zeus shell.

7. Reports

7.1.1. The user shall be able to capture a print screen of the current display to the windows clipboard.

7.1.2. The user shall be able to initiate an ECG report from the Zeus.

Note: Future clinical rounds reports shall be available through the Prometheus. However, there shall be the need to trigger standard monitoring recordings, laser printouts and reports.

8. System Messages

8.1.1. ~~The following Windows NT messages shall be displayed: 11BD~~

8.1.2. ~~The following Zeus System Messages shall be displayed: 11BD~~

9. Service Requirements

9.1.1. Service Strategy

The primary Technical Service and Support (TSS) service strategy is to provide PCS products that are easy to install, maintain, and troubleshoot. It is our goal to reduce the costs of service and simultaneously improve the quality of the service. This can be accomplished by building service software into the product. Benefits of service software are many:

- system access from the network (including dial in access),
- problems can be identified from offsite personnel,
- decreased repair time, higher first time fix rate,
- software updates can be performed over the network,
- software upgrades can be performed over the network,
- improved customer acceptance for service contracts.

9.2. Service Definitions

MTBF Mean Time Between Failure. A prognosis with respect to the average time during which the product or system in the installed base functions without errors, that is, according to its assured characteristics.

MTBSC Mean Time Between Service Calls. The actual value of the average time between service calls. It is used as a long-term comparative value for purposes of product monitoring. The MTBSC includes all service activities, i.e. system downtime, software errors, incorrect operation, and climatic influences, but not upgrades, updates, preventive maintenance or retrofits.

MTTR Mean Time To Repair. The average repair time which is necessary in order to correct a malfunction and restore the assured product or system characteristics. It considers only the repair time, and not logistics times such as travel time, wait time, set-up time, disposition time, etc.

MTTM Mean Time To Maintain. The average time required for preventive maintenance and for performing safety tests on a product or system. Time required for error correction is not included.

Update. A technical change without a functional expansion.

Upgrade. A technical change with a functional expansion.

9.3. Service User Interface

- 9.3.1. Service software for the system shall be completely integrated in the system.
- 9.3.2. Software development and maintenance shall be performed by the responsible R&D department.
- 9.3.3. A service UI shall be developed with a menu of service tools. Service software shall offer the same look and feel for local and remote access.
- 9.3.4. **Service/BioMed menu: TBD**

9.4. Service Access Control

- 9.4.1. It shall be possible to access the service software from the local system console as well as from a remote computer with the same user interface.
- 9.4.2. It shall be impossible to use the service software or parts of the service software without a valid service license.

9.5. Service session monitor

- 9.5.1. The service session monitor shall monitor:
 - 9.5.1.1. Date and time of login
 - 9.5.1.2. Date and time of logout

9.6. Service site information

- 9.6.1. A user interface for setting service related site specific values shall be provided within the service software package (handing over date, system serial number, etc)
- 9.6.2. During a service session these values (site specific values) shall be displayed in the service UI, thus a service person can identify the system that he/she is connected too.

9.7. Service customer information

- 9.7.1. In case of problems the customer shall have information about hotline and identification data of the site. A service UI shall be available to set those values.

9.8. Utilities

- 9.8.1. It shall be possible to monitor system resources: memory usage, disk space, process status. It must be possible to access software versions, installed options, serial numbers, etc)
- 9.8.2. It shall be possible to transfer software updates and upgrades from the network, via a remote computer (the multiview workstation for example), via CDROM, or via a PCMCIA card.
- 9.8.3. When the new software has been successfully transferred to the system, the installation shall be started from a remote computer.
- 9.8.4. Within the service software it shall be possible to:
- restart the application,
 - shutdown and restart the operating system.
- 9.8.5. File transfer of logs from the system to a remote computer system and vice versa (netInfo).
- 9.8.6. A configuration file shall be maintained with the current Zeus setups. This file shall be used for troubleshooting.--

9.9. Hardware Interfaces

- 9.9.1. Components shall be designed so that they can be separated at interfaces without special tools.
- 9.9.2. The internal mechanical interfaces shall be provide for easy removal of spare parts, should they need to be replaced (disk and memory).
- 9.9.3. The hard disk and memory shall be replacable in 5 minutes or less in the field by a service technician.

9.10. Fuses

- 9.10.1. All fuses shall be easily accessible and visible

9.11. Configuration

- 9.11.1. Hardware configurations shall be avoided. If not, the jumpers (jumper diagram shall be supplied), switches, etc. shall be placed so that they are easily accessible.
- 9.11.2. The jumpers on PC board modules should be plug-in type, wrapping shall not be allowed.
- 9.11.3. If jumpers must be plugged in, then the boards shall be coded accordingly.

9.12. VisualDisplays

- 9.12.1. The color scheme for LED's shall be as follows:
 - Red = malfunction
 - Green = ready
 - Yellow = status display
- 9.12.2. Initial testing for the following functions shall be possible via LED's:
 - voltage supply
 - activation of drives (right, left, etc.)
- 9.12.3. LED's shall be positioned and labeled so that they are easy to see and identify.
- 9.12.4. For PC plug-in cards, the LED's shall be visible through the slot.

9.13. Reliability

- 9.13.1. Information on the anticipated frequency of product malfunction, expressed by the MTBSC and MTBF shall be provided. The reliability objectives are determined in the product Requirement Specifications.

9.14. Error Concept

- 9.14.1. A maximum of help shall be made available to the user so that they can bring the system back to its normal operating condition as quickly as possible. Thus, the following shall be required:
 - 9.14.1.1. Each error display shall provide information to the user about what must be done next to correct the error situation.
 - 9.14.1.2. The display shall be designed as follows:
 - 9.14.1.2.1. Limitation of the function
 - 9.14.1.2.2. Corrective measure
 - 9.14.1.2.2.1. The display shall be in the local national language (configurable).
 - 9.14.1.2.2.2. In order to let the user recognize whether the display is an operating prompt or an error situation, an appropriate difference in the type of display shall be selected.

9.14.2. An error message shall be contain at least the following information:

- 9.14.2.1. Error class (severity)
- 9.14.2.2. Date, time
- 9.14.2.3. Error source (source)
- 9.14.2.4. Error number (message ID)
- 9.14.2.5. Text

Note: Windows NT defines the following error classes (severity):

- Success
- Information
- Warning
- Error

9.14.3. Since the MedCom service software shall be used as the common user interface for many future projects and many requirements for error display for the service technician have already been implemented in it, this structure should also be used in non MedCom-based systems.

Example of a MedCom error message as it appears in the event log:

**E 02-03-1998 07:51:38 Application CT_XRS 32 Generator error [E 50 01 20
FF FF FF]**

Here, the individual elements mean:

E Severity

02-03-1998 Date

07:51:38 Time

Application Domain

CT_XRS Source, includes the modality, subsystem

32 Message ID, error detection, must be unmistakable

Generator.. Text static

[E 50 01 20 ... Text dynamic

9.15. Message ID

9.15.1. Since the error text that can be displayed may not always be sufficient, a display of the error number (messageID shall be required so the error can be reported to the USC.

Note: This unmistakable error number becomes even more important because it must be assumed that not all systems are always be equipped with a remote connection.

9.16. Messages

- 9.16.1. There shall be a brief message text providing information to the service technician.
- 9.16.2. There shall be a detailed message text providing expanded information for the service technician. The first source of information for the service technician about the possible causes of errors is the expanded error text.
- 9.16.3. This error text shall provide information about the cause of the error that is as precise as possible.
- 9.16.4. When a mouse click is made on the error number (Message ID), the expanded error text shall open in the event log reader which shall be saved separately as an HTML file in a "pool" directory for each error number.
- 9.16.5. The following criteria shall be met:
 - 9.16.5.1. An expanded error text shall be provided for each error message.
 - 9.16.5.2. The expanded error text shall always be displayed in the form of a table with the same format.
 - 9.16.5.3. The expanded error text shall explain as exactly as possible the cause of the error, its effect and a corrective measure in a form that is understandable for the service technician.
 - 9.16.5.4. For hardware errors, it shall be oriented towards the replaceable unit (FRU / spare part) or the service measure.
 - 9.16.5.5. If no clear statement can be made in the corrective measures, the measures shall be prioritized so that replacement of parts that are not defective is avoided (hierarchy for FRU's).

9.17. Event Log

- 9.17.1. All error messages shall be stored centrally in the event log.
To have the errors saved in the order in which they occurred, every error message shall be provided with a date/time stamp.
- 9.17.2. This time stamp shall be assigned by the subsystem before the error message is sent to the central error management (time at which the error was generated, not the time that it was saved in the event log).
- 9.17.3. The Prerequisite for this is that each subsystem shall be synchronized with the system time and appropriate accuracy of the time is used.
- 9.17.4. The space for saving the log files shall be sufficient to handle a time period of at least seven days.

9.18. Events to be Saved

The following requirement shall be observed:

- 9.18.1. Events which shall be saved on a standard basis
 - 9.18.1.1. Errors in the Warning and Error classes
 - 9.18.1.2. Start and end of the service session (as info)
 - 9.18.1.3. Start and end of the remote access session (as info)
- 9.18.2. Among other things, the following additional items shall be events:
 - 9.18.2.1. Reset /boot of the system (bootup / shutdown)
 - 9.18.2.2. Creation of a new patient (folder)

- 9.18.2.3. Use data
- 9.18.2.4. User events
- 9.18.2.5. Operating errors

9.18.3. These additional events shall be saved under Info or Success.

9.18.4. The decision about which additional events need to be saved in the system event log or whether additional log files are to be used for shall be made within the modality.

9.18.5. The event log can not be configured, i.e. the defined events are always saved.

9.19. Reading Out the Event Log (Log Reader)

Note: By carrying out very targeted analysis / statistical evaluations of the event log, appropriate information can be won from these events. For example, an analysis of the use data can provide a statement about the use of certain operating modes by the user, or the evaluation of the stored operating errors makes it possible to gain an insight about weak points in system operation.

9.19.1. The MedCom "Event Log Reader" is used as the log reader. This event log reader shall be able to be started in the MedCom service user interface. Even in systems in which "MedCom-Service" is not used, a similar form of the event log reader shall be used.

9.19.2. The event log reader shall provide the following functions:

- 9.19.2.1. Domain: All, System, Security, Application (selectable)
- 9.19.2.2. Severity: All, Information, Error, Warning, Success (selectable)
- 9.19.2.3. Search: pattern Search String (text entry), e.g. FATAL
- 9.19.2.4. Process name: e.g. business division and component/subsystem (text entry)
- 9.19.2.5. Message: ID error number (text entry)
- 9.19.2.6. Message limit: max. displayed messages (entry)
- 9.19.2.7. Date: date range from - to (entry)
- 9.19.2.8. Toggle Time : makes it possible to filter to a time range from - to (hour / minute)
- 9.19.2.9. Sequence: sorting sequence, newest, oldest first
- 9.19.2.10. The log reader must make it possible to extract the filtered entries into a file (Extract to).
- 9.19.2.11. After entry of a message ID and source, it shall be possible to display the corresponding error text / expanded error text in the log reader.

9.20. Status Log

Status Log is to be understood as a storage of the system status prior to occurrence of an error. By analyzing the status log, the exact cause of the error, particularly with sporadic errors, can be found more easily because the circumstances and conditions which normally led to the error have also been saved. From this, the error situation can be recreated and analyzed in other systems. This function (saving the status ((operating steps, etc.)) prior to a fatal error) has not yet been implemented in MedCom.

- 9.20.1. This status log shall be required for a general error concept, however because of the complexity of the analysis, for the most part, this should be regarded as a tool for Engineering and for product specialists in the HSC, but not for the service technician on site.

- 9.20.2. The following functions shall be required for the status log:

Note: The following events are written into the status log: operating steps, communication and system status. The decision of what exactly shall be traced must be defined specifically by the business division.

- 9.20.2.1. The status log has a defined capacity which is dimensioned so that with normal operation by the user, at least the last 5 minutes shall be traced (FIFO buffer).
- 9.20.2.2. If the status log reaches its maximum capacity, the oldest entries shall be deleted.
- 9.20.2.3. The status log shall be saved on the hard drive under the following circumstances:
- 9.20.2.3.1. In a situation where there is a "Fatal" error
- 9.20.2.3.2. When a configured event takes place
- 9.20.2.3.3. At the "press of a key" by the user.
- 9.20.2.4. The file name of the saved status log shall contain the date and time.
- 9.20.2.5. Following bootup or saving of the status log, a new status log file shall be begun.
- 9.20.2.6. The status log shall be transferred using the remote and auto reporting functions.

9.21. OEM

- 9.21.1. Service on the OEM product shall be performed by TSS and Siemens Field Service Engineers.

9.21.2. Documentation

- 9.21.2.1. Service documentation shall be in English.
- 9.21.2.2. Service documentation shall be made available in an electronic format.
- 9.21.2.3. A product description shall be provided by the OEM.
- 9.21.2.4. Operating instructions shall be provided by the OEM.
- 9.21.2.5. System and block diagrams shall be provided by the OEM.
- 9.21.2.6.

9.21.3. Training

- 9.21.3.1. Service training for TSS on the OEM product shall be made available by the OEM.

9.21.4. Escalation procedures

- 9.21.4.1. Complaint handling shall be escalated to the OEM by QA.

9.21.5. Service tools

- 9.21.5.1. Service for the OEM product shall be with standard tools.
- 9.21.5.2. Service software shall be provided to TSS. The service software shall differentiate between hardware and software problems

9.21.6. There shall be LED's for power.

9.21.7. The OEM BIOS shall do a self test on bootup.

9.21.8. Spare parts

9.21.8.1. A recommended spare parts list shall be defined by TSS. (spare parts are: daughter board, power board, memory, disks, batter, batter trap door, speaker, keyboard, mouse. Note: the main processing board is not a spare part).

9.21.8.2. Defined spare parts shall be available for 5 years by the OEM.

9.21.8.3. The OEM shall be responsible for upward and downward compatibility of spare parts.

9.21.9. Revisions

Any revisions of documentation list above shall be prepared by the OEM and delivered to TSS.

10. System Requirements

10.1.1. Zeus

10.1.1.1. The Zeus shall not cause pre-VE1 Apollo monitors to reset upon opening connection between the devices.

10.1.2. Prometheus

10.1.2.1. The user shall be able to start the Prometheus without having to login.

The user shall be able to start the Prometheus and automatically display the local patient chart.

10.1.3. Apollo

10.1.3.1. The Apollo shall send parameters (all available parameters) and waveforms (up to 32) available to the Zeus.

11. Zeus Requirements Issues :

Remedy Data Base:

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